Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.6.A

EXPLANTATION (REMOVAL) FOR ANY REASON REGARDLESS OF REPLACEMENT: COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Age (years) | 1.001 | 0.9787 |
| Race | | 0.3361 |
| Caucasian | 1.000 (reference) | |
| Other | 0.366 | |
| Smoking Status | | 0.8217 |
| No | 1.000 (reference) | |
| Yes | 0.885 | |
| Surgical Approach | | 0.0427 |
| Inframammary | 1.000 (reference) | |
| Periareoloar | 0.735 | |
| Transaxillary | 2.501 | |
| Mastectomy Scar | N/A | |
| Other/Mixed | 8.596 | |
| Surgical Placement | | 0.9935 |
| Submuscular/Subpectoral | 1.000 (reference) | |
| Subglandular | 0.995 | |
| Other/Mixed | N/A | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not.associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.6.A

EXPLANTATION (REMOVAL) FOR ANY REASON REGARDLESS OF REPLACEMENT: COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Incision Size (cm) | 0.965 | 0.8612 |
| Surface Type | | |
| Smooth | 1.000 (reference) | |
| Textured | 2.194 | |
| Mixed | N/A | |
| Prior Tissue Expander* | | |
| Yes | | |
| No | N/A | |
| Irrigation Solutions Used in Pocket | | 0.8068 |
| Saline Only | 1.000 (reference) | |
| Steroid Only | 0.000 | |
| Antibiotic Only | 1.646 | |
| Drug Only | 9.011 | |
| Other | 4.456 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.6.A

EXPLANTATION (REMOVAL) FOR ANY REASON REGARDLESS OF REPLACEMENT: COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Implant Size | | 0.3472 |
| <=349 cc | N/A | |
| 350-399 cc | 2.147 | |
| 400-499 cc | 1.808 | |
| 500-599 cc | 6.104 | |
| >=600 cc | 0.000 | |
| Site | | 0.9855 |
| Pooled Site | 1.000 (reference) | |
| Site 1 | 1.326 | |
| Site 2 | 0.449 | |
| Site 3 | 0.493 | |
| Site 4 | 0.482 | |
| Site 5 | 0.000 | |
| Site 7 | 1.644 | |
| Site 8 | 0.000 | |
| Site 10 | 0.241 | |
| Site 12 | 0.000 | |
| Site 13 | 0.471 | |
| Site 15 | 0.902 | |
| Site 18 | 0.395 | |
| Site 19 | N/A | |
| Site 23 | 1.318 | |
| Site 30 | N/A | |
| Site 33 | N/A | |
| Site 48 | N/A | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08.58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.7.A

EXPLANTATION (REMOVAL) FOR ANY REASON WITH REPLACEMENT. COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Age (years) | 1.015 | 0.6722 |
| Race | | 0.6875 |
| Caucasian | 1.000 (reference) | |
| Other | 0.649 | |
| Smoking Status | | 0.6368 |
| No | 1.000 (reference) | |
| Yes | 0.719 | |
| Surgical Approach | | 0.0910 |
| Inframammary | 1.000 (reference) | |
| Periareoloar | 0.794 | |
| Transaxillary | 2.647 | |
| Mastectomy Scar | N/A | |
| Other/Mixed | 11.685 | |
| Surgical Placement | | 0.7280 |
| Submuscular/Subpectoral | 1.000 (reference) | |
| Subglandular | 0.779 | |
| Other/Mixed | N/A | |



* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.7.A

EXPLANTATION (REMOVAL) FOR ANY REASON WITH REPLACEMENT: COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Incision Size (cm) | 0.882 | 0.6638 |
| Surface Type | | |
| Smooth | 1.000 (reference) | |
| Textured | 1.425 | |
| Mixed | N/A | |
| Prior Tissue Expander* | | |
| Yes | | |
| No | N/A | |
| Irrigation Solutions Used in Pocket | | 0.9612 |
| Saline Only | 1.000 (reference) | |
| Steroid Only | 0.000 | |
| Antibiotic Only | 0.807 | |
| Drug Only | 1.079 | |
| Other | 2.117 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.7.A

EXPLANTATION (REMOVAL) FOR ANY REASON WITH REPLACEMENT: COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Implant Size | | 0.5319 |
| <=349 cc | N/A | |
| 350-399 cc | 3.044 | |
| 400-499 cc | 1.984 | |
| 500-599 cc | 5.966 | |
| >=600 cc | 0.000 | |
| Site | | 0.9988 |
| Pooled Site | 1.000 (reference) | |
| Site 1 | 0.788 | |
| Site 2 | 0.333 | |
| Site 3 | 0.654 | |
| Site 4 | 1.228 | |
| Site 5 | 0.000 | |
| Site 7 | 1.716 | |
| Site 8 | 0.000 | |
| Site 10 | 0.290 | |
| Site 12 | 0.000 | |
| Site 13 | 0.577 | |
| Site 15 | 0.909 | |
| Site 18 | 0.000 | |
| Site 19 | N/A | |
| Site 23 | 0.295 | |
| Site 30 | N/A | |
| Site 33 | N/A | |
| Site 48 | N/A | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.8.A

EXPLANTATION (REMOVAL) FOR ANY REASON WITHOUT REPLACEMENT: COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Age (years) | 0.970 | 0.4646 |
| Race | | 0.9959 |
| Caucasian | 1.000 (reference) | |
| Other | 0.000 | |
| Smoking Status | | 0.8756 |
| No | 1.000 (reference) | |
| Yes | 0.856 | |
| Surgical Approach | | 0.6603 |
| Inframammary | 1.000 (reference) | |
| Periareoloar | 0.641 | |
| Transaxillary | 1.468 | |
| Mastectomy Scar | N/A | |
| Other/Mixed | 6.307 | |
| Surgical Placement | | 0.6064 |
| Submuscular/Subpectoral | 1.000 (reference) | |
| Subglandular | 1.896 | |
| Other/Mixed | N/A | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.8.A

EXPLANTATION (REMOVAL) FOR ANY REASON WITHOUT REPLACEMENT. COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Incision Size (cm) | 1.092 | 0.7388 |
| Surface Type | | |
| Smooth | 1.000 (reference) | |
| Textured | 2.582 | |
| Mixed | N/A | |
| Prior Tissue Expander* | | |
| Yes | | |
| No | N/A | |
| Irrigation Solutions Used in Pocket | | 0.9889 |
| Saline Only | 1.000 (reference) | |
| Steroid Only | >100 | |
| Antibiotic Only | >100 | |
| Drug Only | >100 | |
| Other | >100 | |

Program Name. Q.\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not.associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.8.A

EXPLANTATION (REMOVAL) FOR ANY REASON WITHOUT REPLACEMENT: COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Implant Size | | 0.6721 |
| <=349 cc | N/A | |
| 350-399 cc | 1.957 | |
| 400-499 cc | 1.556 | |
| 500-599 cc | 6.895 | |
| >=600 cc | 0.353 | |
| Site | | 0.9995 |
| Pooled Site | 1.000 (reference) | |
| Site 1 | 2.208 | |
| Site 2 | 0.734 | |
| Site 3 | 0.000 | |
| Site 4 | 0.000 | |
| Site 5 | 0.000 | |
| Site 7 | 1.357 | |
| Site 8 | 0.125 | |
| Site 10 | 0.000 | |
| Site 12 | 0.000 | |
| Site 13 | 0.000 | |
| Site 15 | 0.753 | |
| Site 18 | 3.130 | |
| Site 19 | N/A | |
| Site 23 | 5.060 | |
| Site 30 | N/A | |
| Site 33 | N/A | |
| Site 48 | N/A | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.9.A

ANY REOPERATION TO THE BREAST OR SURROUNDING AREAS: COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Age (years) | 1.009 | 0.5623 |
| Race | | 0.5698 |
| Caucasian | 1.000 (reference) | |
| Other | 0.800 | |
| Smoking Status | | 0.3523 |
| No | 1.000 (reference) | |
| Yes | 0.736 | |
| Surgical Approach | | 0.0058 |
| Inframammary | 1.000 (reference) | |
| Periareoloar | 0.622 | |
| Transaxillary | 1.260 | |
| Mastectomy Scar | N/A | |
| Other/Mixed | 5.142 | |
| Surgical Placement | | 0.6281 |
| Submuscular/Subpectoral | 1.000 (reference) | |
| Subglandular | 1.158 | |
| Other/Mixed | N/A | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.9.A

ANY REOPERATION TO THE BREAST OR SURROUNDING AREAS: COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Incision Size (cm) | 0.954 | 0.5953 |
| Surface Type | | |
| Smooth | 1.000 (reference) | |
| Textured | 0.874 | |
| Mixed | N/A | |
| Prior Tissue Expander* | | |
| Yes | | |
| No | N/A | |
| Irrigation Solutions Used in Pocket | | 0.0996 |
| Saline Only | 1.000 (reference) | |
| Steroid Only | 0.000 | |
| Antibiotic Only | 0.536 | |
| Drug Only | 7.861 | |
| Other | 2.840 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.9.A

ANY REOPERATION TO THE BREAST OR SURROUNDING AREAS: COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Implant Size | | 0.8376 |
| <=349 cc | N/A | |
| 350-399 cc | 0.803 | |
| 400-499 cc | 0.753 | |
| 500-599 cc | 1.267 | |
| >=600 cc | 0.000 | |
| Site | | 0.4277 |
| Pooled Site | 1.000 (reference) | |
| Site 1 | 1.783 | |
| Site 2 | 0.446 | |
| Site 3 | 0.471 | |
| Site 4 | 0.959 | |
| Site 5 | 1.788 | |
| Site 7 | 0.282 | |
| Site 8 | 0.296 | |
| Site 10 | 0.270 | |
| Site 12 | 0.121 | |
| Site 13 | 0.253 | |
| Site 15 | 0.528 | |
| Site 18 | 0.164 | |
| Site 19 | N/A | |
| Site 23 | 0.289 | |
| Site 30 | N/A | |
| Site 33 | N/A | |
| Site 48 | N/A | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.10.A

ANY COMPLICATION: COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Age (years) | 1.001 | 0.8962 |
| Race | | 0.0956 |
| Caucasian | 1.000 (reference) | |
| Other | 1.445 | |
| Smoking Status | | 0.4934 |
| No | 1.000 (reference) | |
| Yes | 0.871 | |
| Surgical Approach | | 0.0936 |
| Inframammary | 1.000 (reference) | |
| Periareoloar | 0.669 | |
| Transaxillary | 1 012 | |
| Mastectomy Scar | N/A | |
| Other/Mixed | 2.457 | |
| Surgical Placement | | 0.7307 |
| Submuscular/Subpectoral | 1.000 (reference) | |
| Subglandular | 1.071 | |
| Other/Mixed | N/A | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note. Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10 10.A

ANY COMPLICATION: COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Incision Size (cm) | 1.012 | 0.8480 |
| Surface Type | | |
| Smooth | 1.000 (reference) | |
| Textured | 1.518 | |
| Mixed | N/A | |
| Prior Tissue Expander* | | |
| Yes | | |
| No | N/A | |
| Irrigation Solutions Used in Pocket | | 0.8992 |
| Saline Only | 1.000 (reference) | |
| Steroid Only | 2.557 | |
| Antibiotic Only | 1.274 | |
| Drug Only | 1.194 | |
| Other | 1.461 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.10.A

ANY COMPLICATION. COX REGRESSION

| | Augmentation Patients | |
|---|---|---|
| Explanatory Variables | Estimated Hazard Ratio | p-value |
| Implant Size | | 0.5244 |
| <=349 cc | N/A | |
| 350-399 cc | 0.767 | |
| 400-499 cc | 0.821 | |
| 500-599 cc | 1.302 | |
| >=600 cc | 0.759 | |
| Site | | 0.9269 |
| Pooled Site | 1.000 (reference) | |
| Site 1 | 1.136 | |
| Site 2 | 0.910 | |
| Site 3 | 0.698 | |
| Site 4 | 0.759 | |
| Site 5 | 1.101 | |
| Site 7 | 0.576 | |
| Site 8 | 1.458 | |
| Site 10 | 0.680 | |
| Site 12 | 0.492 | |
| Site 13 | 1.182 | |
| Site 15 | 0.894 | |
| Site 18 | 0.831 | |
| Site 19 | N/A | |
| Site 23 | 0.700 | |
| Site 30 | N/A | |
| Site 33 | N/A | |
| Site 48 | N/A | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08.58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.1

INCIDENCE OF RHEUMATIC DISEASE NEWLY DIAGNOSED BY A RHEUMATOLOGIST
AUGMENTATION PATIENTS

| Type of Diagnoses | 0-12 months (a) Number of Patients n(%) | >12-24 months (a) Number of Patients n(%) | >24-36 months (a) Number of Patients n(%) | 0-36 months (a) Number of Patients n(%) |
|---|---|---|---|---|
| Total with at Least One New Diagnosis of Rheumatic Disease | 0 ( 0) | 3 ( 0.5) | | 3 ( 0.5) |
| INFLAMMATORY ARTHRITIS: | | | | |
| RHEUMATOID ARTHRITIS | 0 ( 0) | 1 ( 0.2) | | 1 ( 0.2) |
| OTHERS: | | | | |
| HASHIMOTO'S THYROIDITIS | 0 ( 0) | 1 ( 0.2) | | 1 ( 0.2) |
| HYPOTHYROIDISM | 0 ( 0) | 1 ( 0.2) | | 1 ( 0.2) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.1

INCIDENCE OF RHEUMATIC DISEASE NEWLY DIAGNOSED BY A RHEUMATOLOGIST
RECONSTRUCTION PATIENTS

| Type of Diagnoses | 0-12 months (a) Number of Patients n(%) | >12-24 months (a) Number of Patients n(%) | >24-36 months (a) Number of Patients n(%) | 0-36 months (a) Number of Patients n(%) |
|---|---|---|---|---|
| Total with at Least One New Diagnosis of Rheumatic Disease | 1 ( 0.4) | 0 ( 0) | | 1 ( 0.4) |
| NON-INFLAMMATORY RHEUMATIC CONDITIONS: FIBROMYALGIA | 1 ( 0.4) | 0 ( 0) | | 1 ( 0.4) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.1

INCIDENCE OF RHEUMATIC DISEASE NEWLY DIAGNOSED BY A RHEUMATOLOGIST
REVISION PATIENTS

| Type of Diagnoses | 0-12 months (a) Number of Patients n(%) | >12-24 months (a) Number of Patients n(%) | >24-36 months (a) Number of Patients n(%) | 0-36 months (a) Number of Patients n(%) |
|---|---|---|---|---|
| Total with at Least One New Diagnosis of Rheumatic Disease | 2 ( 1.0) | 0 ( 0) | | 2 ( 1.0) |
| NON-INFLAMMATORY RHEUMATIC CONDITIONS: | | | | |
| FIBROMYALGIA | 1 ( 0.5) | 0 ( 0) | | 1 ( 0.5) |
| OTHERS: | | | | |
| PYODERMA GANGRENOSUM | 1 ( 0.5) | 0 ( 0) | | 1 ( 0.5) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.1

INCIDENCE OF RHEUMATIC DISEASE NEWLY DIAGNOSED BY A RHEUMATOLOGIST
OVERALL PATIENTS

| Type of Diagnoses | 0-12 months (a) Number of Patients n(%) | >12-24 months (a) Number of Patients n(%) | >24-36 months (a) Number of Patients n(%) | 0-36 months (a) Number of Patients n(%) |
|---|---|---|---|---|
| Total with at Least One New Diagnosis of Rheumatic Disease | 3 ( 0.3) | 3 ( 0.3) | | 6 ( 0.6) |
| INFLAMMATORY ARTHRITIS: | | | | |
| RHEUMATOID ARTHRITIS | 0 ( 0) | 1 ( 0.1) | | 1 ( 0.1) |
| NON-INFLAMMATORY RHEUMATIC CONDITIONS: | | | | |
| FIBROMYALGIA | 2 ( 0.2) | 0 ( 0) | | 2 ( 0.2) |
| OTHERS: | | | | |
| HASHIMOTO'S THYROIDITIS | 0 ( 0) | 1 ( 0.1) | | 1 ( 0.1) |
| HYPOTHYROIDISM | 0 ( 0) | 1 ( 0.1) | | 1 ( 0.1) |
| PYODERMA GANGRENOSUM | 1 ( 0.1) | 0 ( 0) | | 1 ( 0.1) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.2

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM BY SYSTEM CATEGORY
AUGMENTATION PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic System Category | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| Total with at Least One New Rheumatologic System Category | 21 ( 3.8) | 25 ( 4.5) | 17 ( 3.1) | 51 ( 9.3) |
| Skin and Appendages | 2 ( 0.4) | 4 ( 0.7) | 4 ( 0.7) | 10 ( 1.8) |
| Muscle | 6 ( 1.1) | 7 ( 1.3) | 5 ( 0.9) | 18 ( 3.3) |
| Joint | 3 ( 0.5) | 8 ( 1.5) | 3 ( 0.5) | 14 ( 2.5) |
| CNS | 7 ( 1.3) | 8 ( 1.5) | 5 ( 0.9) | 20 ( 3.6) |
| Gastrointestinal | 1 ( 0.2) | 2 ( 0.4) | 1 ( 0.2) | 4 ( 0.7) |
| Body as a Whole | 4 ( 0.7) | 10 ( 1.8) | 4 ( 0.7) | 18 ( 3.3) |
| Metabolic and Nutritional | 0 ( 0) | 1 ( 0.2) | 1 ( 0.2) | 2 ( 0.4) |
| Hearing and Vestibular | 1 ( 0.2) | 5 ( 0.9) | 1 ( 0.2) | 7 ( 1.3) |
| Respiratory | 0 ( 0) | 2 ( 0.4) | 0 ( 0) | 2 ( 0.4) |
| Platelet, Bleeding, Clotting Disorder | 1 ( 0.2) | 0 ( 0) | 1 ( 0.2) | 2 ( 0.4) |
| Cardiovascular | 1 ( 0.2) | 0 ( 0) | 0 ( 0) | 1 ( 0.2) |
| Vision | 2 ( 0.4) | 2 ( 0.4) | 0 ( 0) | 4 ( 0.7) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.2

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM BY SYSTEM CATEGORY
RECONSTRUCTION PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic System Category | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| Total with at Least One New Rheumatologic System Category | 20 ( 8.0) | 18 ( 7.2) | 5 ( 2.0) | 40 (15.9) |
| Skin and Appendages | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) | 2 ( 0.8) |
| Muscle | 6 ( 2.4) | 6 ( 2.4) | 2 ( 0.8) | 14 ( 5.6) |
| Joint | 9 ( 3.6) | 6 ( 2.4) | 0 ( 0) | 15 ( 6.0) |
| CNS | 1 ( 0.4) | 2 ( 0.8) | 1 ( 0.4) | 4 ( 1.6) |
| Gastrointestinal | 0 ( 0) | 0 ( 0) | 1 ( 0.4) | 1 ( 0.4) |
| Body as a Whole | 6 ( 2.4) | 9 ( 3.6) | 2 ( 0.8) | 17 ( 6.8) |
| Metabolic and Nutritional | 1 ( 0.4) | 0 ( 0) | 0 ( 0) | 1 ( 0.4) |
| Hearing and Vestibular | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) |
| Platelet, Bleeding, Clotting Disorder | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) |
| Vision | 1 ( 0.4) | 1 ( 0 4) | 0 ( 0) | 2 ( 0.8) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11 2

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM BY SYSTEM CATEGORY
REVISION PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic System Category | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| Total with at Least One New Rheumatologic System Category | 17 ( 8.3) | 17 ( 8.3) | 8 ( 3.9) | 36 (17.6) |
| Skin and Appendages | 3 ( 1.5) | 2 ( 1.0) | 3 ( 1.5) | 8 ( 3.9) |
| Muscle | 5 ( 2.4) | 7 ( 3.4) | 3 ( 1.5) | 15 ( 7.3) |
| Joint | 4 ( 2.0) | 6 ( 2.9) | 0 ( 0) | 10 ( 4.9) |
| CNS | 5 ( 2.4) | 8 ( 3.9) | 1 ( 0.5) | 14 ( 6.8) |
| Gastrointestinal | 2 ( 1.0) | 3 ( 1.5) | 0 ( 0) | 5 ( 2.4) |
| Body as a Whole | 11 ( 5.4) | 11 ( 5.4) | 1 ( 0.5) | 23 (11.2) |
| Metabolic and Nutritional | 1 ( 0.5) | 2 ( 1.0) | 0 ( 0) | 3 ( 1.5) |
| Hearing and Vestibular | 3 ( 1.5) | 1 ( 0.5) | 1 ( 0.5) | 5 ( 2.4) |
| Respiratory | 0 ( 0) | 1 ( 0.5) | 0 ( 0) | 1 ( 0.5) |
| Platelet, Bleeding, Clotting Disorder | 1 ( 0.5) | 2 ( 1.0) | 1 ( 0.5) | 4 ( 2.0) |
| Vision | 0 ( 0) | 2 ( 1.0) | 0 ( 0) | 2 ( 1.0) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.2

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM BY SYSTEM CATEGORY
OVERALL PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic System Category | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| Total with at Least One New Rheumatologic System Category | 58 ( 5.8) | 60 ( 6.0) | 30 ( 3.0) | 127 (12.6) |
| Skin and Appendages | 6 ( 0.6) | 6 ( 0.6) | 8 ( 0.8) | 20 ( 2 0) |
| Muscle | 17 ( 1.7) | 20 ( 2.0) | 10 ( 1.0) | 47 ( 4.7) |
| Joint | 16 ( 1.6) | 20 ( 2.0) | 3 ( 0.3) | 39 ( 3.9) |
| CNS | 13 ( 1.3) | 18 ( 1.8) | 7 ( 0.7) | 38 ( 3.8) |
| Gastrointestinal | 3 ( 0.3) | 5 ( 0.5) | 2 ( 0.2) | 10 ( 1 0) |
| Body as a Whole | 21 ( 2.1) | 30 ( 3.0) | 7 ( 0.7) | 58 ( 5.8) |
| Metabolic and Nutritional | 2 ( 0.2) | 3 ( 0.3) | 1 ( 0.1) | 6 ( 0.6) |
| Hearing and Vestibular | 4 ( 0.4) | 7 ( 0.7) | 2 ( 0.2) | 13 ( 1.3) |
| Respiratory | 0 ( 0) | 3 ( 0.3) | 0 ( 0) | 3 ( 0.3) |
| Platelet, Bleeding, Clotting Disorder | 2 ( 0.2) | 3 ( 0.3) | 2 ( 0.2) | 7 ( 0.7) |
| Cardiovascular | 1 ( 0.1) | 0 ( 0) | 0 ( 0) | 1 ( 0.1) |
| Vision | 3 ( 0.3) | 5 ( 0.5) | 0 ( 0) | 8 ( 0.8) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM BY SYMPTOM TYPE
AUGMENTATION PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic Symptom Type | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| Total with at Least One New Rheumatologic Symptom Type | 21 ( 3.8) | 25 ( 4.5) | 17 ( 3.1) | 51 ( 9.3) |
| LOSS OF WEIGHT WITHOUT DIETING | 0 ( 0) | 1 ( 0.2) | 1 ( 0.2) | 2 ( 0.4) |
| FATIGUE | 1 ( 0.2) | 6 ( 1.1) | 2 ( 0.4) | 9 ( 1.6) |
| INSOMNIA | 2 ( 0.4) | 5 ( 0.9) | 1 ( 0.2) | 8 ( 1.5) |
| WEAKNESS | 1 ( 0.2) | 2 ( 0.4) | 0 ( 0) | 3 ( 0.5) |
| EXHAUSTION | 1 ( 0.2) | 3 ( 0.5) | 1 ( 0.2) | 5 ( 0.9) |
| JOINT SWELLING | 1 ( 0.2) | 3 ( 0.5) | 0 ( 0) | 4 ( 0.7) |
| HEEL PAIN | 1 ( 0.2) | 2 ( 0.4) | 2 ( 0.4) | 5 ( 0.9) |
| FREQUENT MUSCLE CRAMPS | 1 ( 0.2) | 3 ( 0.5) | 1 ( 0.2) | 5 ( 0.9) |
| NUMBNESS OF FEET | 1 ( 0.2) | 3 ( 0.5) | 1 ( 0.2) | 5 ( 0.9) |
| RINGING IN EARS | 1 ( 0.2) | 5 ( 0.9) | 1 ( 0.2) | 7 ( 1.3) |
| PAIN/GRITTINESS IN EYES | 2 ( 0.4) | 1 ( 0.2) | 0 ( 0) | 3 ( 0.5) |
| DRYNESS OF EYES/NOSE | 0 ( 0) | 1 ( 0.2) | 0 ( 0) | 1 ( 0.2) |
| NECK PAIN/STIFFNESS | 3 ( 0.5) | 3 ( 0.5) | 3 ( 0.5) | 9 ( 1.6) |
| HEART MURMURS | 1 ( 0.2) | 0 ( 0) | 0 ( 0) | 1 ( 0.2) |
| LOSS OF APPETITE | 0 ( 0) | 1 ( 0.2) | 0 ( 0) | 1 ( 0.2) |
| NIGHT SWEATS | 2 ( 0.4) | 3 ( 0.5) | 2 ( 0.4) | 7 ( 1.3) |
| GENERALIZED ACHING | 0 ( 0) | 4 ( 0.7) | 1 ( 0.2) | 5 ( 0.9) |
| JOINT PAIN | 2 ( 0.4) | 7 ( 1.3) | 3 ( 0.5) | 12 ( 2.2) |
| FREQUENT MUSCLE PAIN | 0 ( 0) | 2 ( 0.4) | 0 ( 0) | 2 ( 0.4) |
| NUMBNESS OF HANDS | 5 ( 0.9) | 5 ( 0.9) | 3 ( 0.5) | 13 ( 2.4) |
| REDNESS OF EYES | 0 ( 0) | 1 ( 0.2) | 1 ( 0.2) | 2 ( 0.4) |
| DRYNESS OF MOUTH | 0 ( 0) | 1 ( 0.2) | 0 ( 0) | 1 ( 0.2) |
| BACK PAIN/STIFFNESS | 2 ( 0.4) | 4 ( 0.7) | 0 ( 0) | 6 ( 1.1) |

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Creation Date, Time: 27JUL04 11:47

(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11 3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM BY SYMPTOM TYPE
AUGMENTATION PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic Symptom Type | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| SEVERE CHEST PAINS | 1 ( 0.2) | 1 ( 0 2) | 0 ( 0) | 2 ( 0.4) |
| CHRONIC COUGH | 0 ( 0) | 2 ( 0.4) | 0 ( 0) | 2 ( 0.4) |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 1 ( 0.2) | 1 ( 0.2) | 1 ( 0.2) | 3 ( 0.5) |
| SEVERE RASHES | 1 ( 0.2) | 2 ( 0.4) | 0 ( 0) | 3 ( 0.5) |
| SEVERE DRYNESS OF SKIN | 1 ( 0.2) | 0 ( 0) | 2 ( 0.4) | 3 ( 0.5) |
| TENDER LUMPS/BUMPS | 0 ( 0) | 1 ( 0.2) | 0 ( 0) | 1 ( 0.2) |
| FREQUENT HIVES | 0 ( 0) | 1 ( 0.2) | 0 ( 0) | 1 ( 0.2) |
| UNUSUAL HAIR LOSS | 0 ( 0) | 1 ( 0.2) | 2 ( 0.4) | 3 ( 0.5) |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | 1 ( 0.2) | 0 ( 0) | 1 ( 0.2) | 2 ( 0.4) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM BY SYMPTOM TYPE
RECONSTRUCTION PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic Symptom Type | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| Total with at Least One New Rheumatologic Symptom Type | 20 ( 8.0) | 19 ( 7.6) | 5 ( 2.0) | 40 (15.9) |
| LOSS OF WEIGHT WITHOUT DIETING | 1 ( 0.4) | 0 ( 0) | 0 ( 0) | 1 ( 0.4) |
| FATIGUE | 2 ( 0.8) | 4 ( 1.6) | 1 ( 0.4) | 7 ( 2.8) |
| INSOMNIA | 1 ( 0.4) | 2 ( 0.8) | 1 ( 0.4) | 4 ( 1.6) |
| WEAKNESS | 0 ( 0) | 0 ( 0) | 1 ( 0.4) | 1 ( 0.4) |
| EXHAUSTION | 0 ( 0) | 2 ( 0.8) | 0 ( 0) | 2 ( 0.8) |
| JOINT SWELLING | 2 ( 0.8) | 3 ( 1.2) | 0 ( 0) | 5 ( 2.0) |
| HEEL PAIN | 0 ( 0) | 1 ( 0.4) | 1 ( 0.4) | 2 ( 0.8) |
| FREQUENT MUSCLE CRAMPS | 3 ( 1.2) | 5 ( 2.0) | 0 ( 0) | 8 ( 3.2) |
| RINGING IN EARS | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) |
| PAIN/GRITTINESS IN EYES | 1 ( 0.4) | 1 ( 0.4) | 0 ( 0) | 2 ( 0.8) |
| DRYNESS OF EYES/NOSE | 1 ( 0.4) | 1 ( 0.4) | 0 ( 0) | 2 ( 0.8) |
| NECK PAIN/STIFFNESS | 0 ( 0) | 2 ( 0.8) | 2 ( 0.8) | 4 ( 1.6) |
| NIGHT SWEATS | 2 ( 0.8) | 2 ( 0.8) | 1 ( 0.4) | 5 ( 2.0) |
| GENERALIZED ACHING | 1 ( 0.4) | 2 ( 0.8) | 0 ( 0) | 3 ( 1.2) |
| LOSS OF HEIGHT | 2 ( 0.8) | 2 ( 0.8) | 0 ( 0) | 4 ( 1.6) |
| JOINT PAIN | 9 ( 3.6) | 5 ( 2.0) | 0 ( 0) | 14 ( 5.6) |
| FREQUENT MUSCLE PAIN | 2 ( 0.8) | 1 ( 0.4) | 0 ( 0) | 3 ( 1.2) |
| JAW PAIN | 0 ( 0) | 0 ( 0) | 1 ( 0.4) | 1 ( 0.4) |
| BACK PAIN/STIFFNESS | 2 ( 0.8) | 1 ( 0.4) | 0 ( 0) | 3 ( 1.2) |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 0 ( 0) | 0 ( 0) | 1 ( 0.4) | 1 ( 0.4) |
| TENDER LUMPS/BUMPS | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) |
| UNUSUAL HAIR LOSS | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) | 2 ( 0.8) |
| TENDERNESS OF SCALP | 1 ( 0.4) | 0 ( 0) | 0 ( 0) | 1 ( 0.4) |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11 3.SAS

Creation Date, Time: 27JUL04 11:47

(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM BY SYMPTOM TYPE
RECONSTRUCTION PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic Symptom Type | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_3.SAS Creation Date, Time. 27JUL04 11:47

(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM BY SYMPTOM TYPE
REVISION PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic Symptom Type | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| Total with at Least One New Rheumatologic Symptom Type | 17 ( 8.3) | 18 ( 8.8) | 8 ( 3.9) | 36 (17.6) |
| LOSS OF WEIGHT WITHOUT DIETING | 1 ( 0.5) | 2 ( 1.0) | 0 ( 0) | 3 ( 1.5) |
| FATIGUE | 5 ( 2.4) | 4 ( 2.0) | 2 ( 1.0) | 11 ( 5.4) |
| INSOMNIA | 2 ( 1.0) | 3 ( 1.5) | 0 ( 0) | 5 ( 2.4) |
| WEAKNESS | 1 ( 0.5) | 3 ( 1.5) | 1 ( 0.5) | 5 ( 2.4) |
| EXHAUSTION | 1 ( 0.5) | 4 ( 2.0) | 1 ( 0.5) | 6 ( 2.9) |
| JOINT SWELLING | 0 ( 0) | 3 ( 1.5) | 1 ( 0.5) | 4 ( 2.0) |
| HEEL PAIN | 2 ( 1.0) | 0 ( 0) | 0 ( 0) | 2 ( 1.0) |
| FREQUENT MUSCLE CRAMPS | 1 ( 0.5) | 3 ( 1.5) | 1 ( 0.5) | 5 ( 2.4) |
| NUMBNESS OF FEET | 2 ( 1.0) | 1 ( 0.5) | 1 ( 0.5) | 4 ( 2.0) |
| RINGING IN EARS | 3 ( 1.5) | 1 ( 0.5) | 1 ( 0.5) | 5 ( 2.4) |
| DRYNESS OF EYES/NOSE | 1 ( 0.5) | 1 ( 0.5) | 0 ( 0) | 2 ( 1.0) |
| PAIN ON SWALLOWING OR CHEWING | 0 ( 0) | 2 ( 1.0) | 0 ( 0) | 2 ( 1.0) |
| NECK PAIN/STIFFNESS | 3 ( 1.5) | 1 ( 0.5) | 0 ( 0) | 4 ( 2.0) |
| PAIN ON BREATHING | 0 ( 0) | 1 ( 0.5) | 0 ( 0) | 1 ( 0.5) |
| LOSS OF APPETITE | 0 ( 0) | 2 ( 1.0) | 0 ( 0) | 2 ( 1.0) |
| NIGHT SWEATS | 3 ( 1.5) | 1 ( 0.5) | 0 ( 0) | 4 ( 2.0) |
| GENERALIZED ACHING | 2 ( 1.0) | 4 ( 2.0) | 1 ( 0.5) | 7 ( 3.4) |
| LOSS OF HEIGHT | 0 ( 0) | 1 ( 0.5) | 0 ( 0) | 1 ( 0.5) |
| JOINT PAIN | 4 ( 2 0) | 6 ( 2.9) | 0 ( 0) | 10 ( 4.9) |
| FREQUENT MUSCLE PAIN | 2 ( 1.0) | 0 ( 0) | 0 ( 0) | 2 ( 1.0) |
| NUMBNESS OF HANDS | 1 ( 0.5) | 6 ( 2.9) | 1 ( 0.5) | 8 ( 3.9) |
| JAW PAIN | 1 ( 0.5) | 0 ( 0) | 0 ( 0) | 1 ( 0.5) |
| REDNESS OF EYES | 0 ( 0) | 2 ( 1.0) | 0 ( 0) | 2 ( 1 0) |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_3.SAS

Creation Date, Time: 27JUL04 11:47

(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM BY SYMPTOM TYPE
REVISION PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic Symptom Type | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| DRYNESS OF MOUTH | 1 ( 0.5) | 1 ( 0.5) | 0 ( 0) | 2 ( 1.0) |
| BACK PAIN/STIFFNESS | 2 ( 1.0) | 4 ( 2.0) | 2 ( 1.0) | 8 ( 3.9) |
| DIFFICULTY SWALLOWING | 0 ( 0) | 2 ( 1.0) | 0 ( 0) | 2 ( 1.0) |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 2 ( 1.0) | 2 ( 1.0) | 0 ( 0) | 4 ( 2.0) |
| SEVERE DRYNESS OF SKIN | 1 ( 0.5) | 2 ( 1.0) | 2 ( 1.0) | 5 ( 2.4) |
| TENDER LUMPS/BUMPS | 2 ( 1.0) | 2 ( 1.0) | 1 ( 0.5) | 5 ( 2.4) |
| EXCESSIVE SENSITIVITY TO SUN | 1 ( 0.5) | 0 ( 0) | 0 ( 0) | 1 ( 0.5) |
| COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE | 1 ( 0.5) | 1 ( 0.5) | 0 ( 0) | 2 ( 1.0) |
| FREQUENT HIVES | 1 ( 0.5) | 0 ( 0) | 0 ( 0) | 1 ( 0.5) |
| UNUSUAL HAIR LOSS | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.5) | 3 ( 1.5) |
| TENDERNESS OF SCALP | 1 ( 0.5) | 0 ( 0) | 0 ( 0) | 1 ( 0.5) |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | 1 ( 0.5) | 2 ( 1.0) | 1 ( 0.5) | 4 ( 2.0) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM BY SYMPTOM TYPE
OVERALL PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic Symptom Type | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| Total with at Least One New Rheumatologic Symptom Type | 58 ( 5.8) | 62 ( 6 2) | 30 ( 3.0) | 127 (12.6) |
| LOSS OF WEIGHT WITHOUT DIETING | 2 ( 0.2) | 3 ( 0.3) | 1 ( 0 1) | 6 ( 0.6) |
| FATIGUE | 8 ( 0.8) | 14 ( 1.4) | 5 ( 0.5) | 27 ( 2.7) |
| INSOMNIA | 5 ( 0.5) | 10 ( 1.0) | 2 ( 0.2) | 17 ( 1.7) |
| WEAKNESS | 2 ( 0.2) | 5 ( 0.5) | 2 ( 0.2) | 9 ( 0.9) |
| EXHAUSTION | 2 ( 0.2) | 9 ( 0.9) | 2 ( 0.2) | 13 ( 1.3) |
| JOINT SWELLING | 3 ( 0.3) | 9 ( 0.9) | 1 ( 0.1) | 13 ( 1.3) |
| HEEL PAIN | 3 ( 0.3) | 3 ( 0.3) | 3 ( 0.3) | 9 ( 0.9) |
| FREQUENT MUSCLE CRAMPS | 5 ( 0.5) | 11 ( 1.1) | 2 ( 0.2) | 18 ( 1.8) |
| NUMBNESS OF FEET | 3 ( 0.3) | 4 ( 0.4) | 2 ( 0.2) | 9 ( 0.9) |
| RINGING IN EARS | 4 ( 0.4) | 7 ( 0.7) | 2 ( 0.2) | 13 ( 1.3) |
| PAIN/GRITTINESS IN EYES | 3 ( 0.3) | 2 ( 0.2) | 0 ( 0) | 5 ( 0.5) |
| DRYNESS OF EYES/NOSE | 2 ( 0.2) | 3 ( 0.3) | 0 ( 0) | 5 ( 0.5) |
| PAIN ON SWALLOWING OR CHEWING | 0 ( 0) | 2 ( 0.2) | 0 ( 0) | 2 ( 0.2) |
| NECK PAIN/STIFFNESS | 6 ( 0.6) | 6 ( 0.6) | 5 ( 0.5) | 17 ( 1.7) |
| PAIN ON BREATHING | 0 ( 0) | 1 ( 0.1) | 0 ( 0) | 1 ( 0.1) |
| HEART MURMURS | 1 ( 0.1) | 0 ( 0) | 0 ( 0) | 1 ( 0.1) |
| LOSS OF APPETITE | 0 ( 0) | 3 ( 0.3) | 0 ( 0) | 3 ( 0.3) |
| NIGHT SWEATS | 7 ( 0.7) | 6 ( 0.6) | 3 ( 0.3) | 16 ( 1.6) |
| GENERALIZED ACHING | 3 ( 0.3) | 10 ( 1.0) | 2 ( 0.2) | 15 ( 1.5) |
| LOSS OF HEIGHT | 2 ( 0.2) | 3 ( 0.3) | 0 ( 0) | 5 ( 0.5) |
| JOINT PAIN | 15 ( 1.5) | 18 ( 1.8) | 3 ( 0.3) | 36 ( 3.6) |
| FREQUENT MUSCLE PAIN | 4 ( 0.4) | 3 ( 0.3) | 0 ( 0) | 7 ( 0.7) |
| NUMBNESS OF HANDS | 6 ( 0.6) | 11 ( 1 1) | 4 ( 0.4) | 21 ( 2.1) |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_3.SAS

Creation Date, Time: 27JUL04 11:47

(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM BY SYMPTOM TYPE
OVERALL PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic Symptom Type | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| JAW PAIN | 1 ( 0.1) | 0 ( 0) | 1 ( 0.1) | 2 ( 0.2) |
| REDNESS OF EYES | 0 ( 0) | 3 ( 0.3) | 1 ( 0.1) | 4 ( 0.4) |
| DRYNESS OF MOUTH | 1 ( 0.1) | 2 ( 0.2) | 0 ( 0) | 3 ( 0.3) |
| BACK PAIN/STIFFNESS | 6 ( 0.6) | 9 ( 0.9) | 2 ( 0.2) | 17 ( 1.7) |
| SEVERE CHEST PAINS | 1 ( 0.1) | 1 ( 0.1) | 0 ( 0) | 2 ( 0.2) |
| CHRONIC COUGH | 0 ( 0) | 2 ( 0.2) | 0 ( 0) | 2 ( 0.2) |
| DIFFICULTY SWALLOWING | 0 ( 0) | 2 ( 0.2) | 0 ( 0) | 2 ( 0.2) |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 3 ( 0.3) | 3 ( 0.3) | 2 ( 0.2) | 8 ( 0.8) |
| SEVERE RASHES | 1 ( 0.1) | 2 ( 0.2) | 0 ( 0) | 3 ( 0.3) |
| SEVERE DRYNESS OF SKIN | 2 ( 0.2) | 2 ( 0.2) | 4 ( 0.4) | 8 ( 0.8) |
| TENDER LUMPS/BUMPS | 2 ( 0.2) | 4 ( 0.4) | 1 ( 0.1) | 7 ( 0.7) |
| EXCESSIVE SENSITIVITY TO SUN | 1 ( 0.1) | 0 ( 0) | 0 ( 0) | 1 ( 0.1) |
| COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE | 1 ( 0.1) | 1 ( 0.1) | 0 ( 0) | 2 ( 0.2) |
| FREQUENT HIVES | 1 ( 0.1) | 1 ( 0.1) | 0 ( 0) | 2 ( 0.2) |
| UNUSUAL HAIR LOSS | 2 ( 0.2) | 2 ( 0.2) | 4 ( 0.4) | 8 ( 0.8) |
| TENDERNESS OF SCALP | 2 ( 0.2) | 0 ( 0) | 0 ( 0) | 2 ( 0.2) |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | 2 ( 0.2) | 3 ( 0.3) | 2 ( 0.2) | 7 ( 0.7) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.4

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE RHEUMATOLOGIC PHYSICAL EXAMINATION FINDINGS
AUGMENTATION PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic Physical Finding | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| Total with at Least One New Rheumatologic Physical Finding | 5 ( 0.9) | 7 ( 1.3) | 6 ( 1.1) | 16 ( 2.9) |
| WEAK HEADLIFT | 1 ( 0.2) | 0 ( 0) | 0 ( 0) | 1 ( 0.2) |
| WRIST SWELLING | 1 ( 0.2) | 0 ( 0) | 0 ( 0) | 1 ( 0.2) |
| DIGITS SWELLING | 2 ( 0.4) | 1 ( 0.2) | 1 ( 0.2) | 4 ( 0.7) |
| KNEES SWELLING | 1 ( 0.2) | 0 ( 0) | 1 ( 0.2) | 2 ( 0.4) |
| ANKLES SWELLING | 0 ( 0) | 1 ( 0.2) | 0 ( 0) | 1 ( 0.2) |
| JOINT TENDERNESS | 1 ( 0.2) | 3 ( 0.5) | 3 ( 0.5) | 7 ( 1.3) |
| HAIR LOSS | 0 ( 0) | 0 ( 0) | 1 ( 0.2) | 1 ( 0.2) |
| SWOLLEN DIGITS | 0 ( 0) | 1 ( 0.2) | 0 ( 0) | 1 ( 0.2) |
| PAINLESS EYE REDNESS | 0 ( 0) | 2 ( 0.4) | 1 ( 0.2) | 3 ( 0.5) |
| MUSCLE TENDERNESS | 0 ( 0) | 1 ( 0.2) | 0 ( 0) | 1 ( 0.2) |
| SKIN RASHES | 0 ( 0) | 1 ( 0.2) | 0 ( 0) | 1 ( 0.2) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.4

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE RHEUMATOLOGIC PHYSICAL EXAMINATION FINDINGS
RECONSTRUCTION PATIENTS

| Rheumatologic Physical Finding | 0-12 months (a) Number of Patients n(%) | >12-24 months (a) Number of Patients n(%) | >24-36 months (a) Number of Patients n(%) | 0-36 months (a) Number of Patients n(%) |
|---|---|---|---|---|
| Total with at Least One New Rheumatologic Physical Finding | 5 ( 2.0) | 8 ( 3.2) | 1 ( 0.4) | 13 ( 5.2) |
| WEAK HEADLIFT | 0 ( 0) | 2 ( 0.8) | 0 ( 0) | 2 ( 0 8) |
| INABILITY TO RAISE ARMS | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) |
| INABILITY TO GET OUT OF CHAIR | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0 4) |
| WRIST SWELLING | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) |
| DIGITS SWELLING | 3 ( 1.2) | 2 ( 0.8) | 0 ( 0) | 5 ( 2.0) |
| ELBOWS SWELLING | 0 ( 0) | 2 ( 0.8) | 0 ( 0) | 2 ( 0.8) |
| KNEES SWELLING | 1 ( 0.4) | 2 ( 0.8) | 0 ( 0) | 3 ( 1.2) |
| ANKLES SWELLING | 1 ( 0.4) | 2 ( 0.8) | 0 ( 0) | 3 ( 1.2) |
| TRIGGER FINGERS | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) |
| JOINT TENDERNESS | 1 ( 0.4) | 3 ( 1.2) | 1 ( 0.4) | 5 ( 2.0) |
| GRIP STRENGTH AND MOTION-FINGER TO PALM CREASE | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) |
| NECK MOTION-CHIN TO CHEST OR STERNUM | 1 ( 0.4) | 1 ( 0.4) | 0 ( 0) | 2 ( 0.8) |
| OCCIPUT TO WALL | 1 ( 0.4) | 1 ( 0.4) | 0 ( 0) | 2 ( 0.8) |
| BACK MOTION | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) |
| HAIR LOSS | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) |
| SWOLLEN DIGITS | 2 ( 0.8) | 2 ( 0.8) | 0 ( 0) | 4 ( 1.6) |
| TENDERNESS-INSERTION OF DELTOIDS | 0 ( 0) | 1 ( 0.4) | 0 ( 0) | 1 ( 0.4) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.4

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE RHEUMATOLOGIC PHYSICAL EXAMINATION FINDINGS
REVISION PATIENTS

| Rheumatologic Physical Finding | 0-12 months (a) Number of Patients n(%) | >12-24 months (a) Number of Patients n(%) | >24-36 months (a) Number of Patients n(%) | 0-36 months (a) Number of Patients n(%) |
|---|---|---|---|---|
| Total with at Least One New Rheumatologic Physical Finding | 7 ( 3.4) | 9 ( 4.4) | 3 ( 1.5) | 18 ( 8.8) |
| WEAK HEADLIFT | 1 ( 0.5) | 0 ( 0) | 0 ( 0) | 1 ( 0.5) |
| INABILITY TO RAISE ARMS | 1 ( 0.5) | 0 ( 0) | 0 ( 0) | 1 ( 0.5) |
| DIGITS SWELLING | 1 ( 0.5) | 2 ( 1.0) | 1 ( 0.5) | 4 ( 2.0) |
| ELBOWS SWELLING | 0 ( 0) | 1 ( 0.5) | 0 ( 0) | 1 ( 0.5) |
| KNEES SWELLING | 0 ( 0) | 2 ( 1.0) | 1 ( 0.5) | 3 ( 1.5) |
| ANKLES SWELLING | 0 ( 0) | 1 ( 0.5) | 0 ( 0) | 1 ( 0.5) |
| BOUTONNIERE | 0 ( 0) | 1 ( 0.5) | 0 ( 0) | 1 ( 0.5) |
| TRIGGER FINGERS | 0 ( 0) | 0 ( 0) | 1 ( 0.5) | 1 ( 0.5) |
| JOINT TENDERNESS | 3 ( 1.5) | 5 ( 2.4) | 0 ( 0) | 8 ( 3.9) |
| NECK MOTION-CHIN TO CHEST OR STERNUM | 1 ( 0.5) | 0 ( 0) | 0 ( 0) | 1 ( 0.5) |
| BACK MOTION | 1 ( 0.5) | 0 ( 0) | 0 ( 0) | 1 ( 0.5) |
| HAIR LOSS | 2 ( 1.0) | 1 ( 0.5) | 0 ( 0) | 3 ( 1.5) |
| RAYNAUD'S PHENOMENON | 1 ( 0.5) | 0 ( 0) | 0 ( 0) | 1 ( 0.5) |
| SWOLLEN DIGITS | 0 ( 0) | 1 ( 0.5) | 0 ( 0) | 1 ( 0.5) |
| MUSCLE TENDERNESS | 0 ( 0) | 1 ( 0.5) | 0 ( 0) | 1 ( 0.5) |
| TINELS OR PHALENS SIGNS | 0 ( 0) | 1 ( 0.5) | 0 ( 0) | 1 ( 0.5) |



(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11 4

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE RHEUMATOLOGIC PHYSICAL EXAMINATION FINDINGS
OVERALL PATIENTS

| | 0-12 months (a) | >12-24 months (a) | >24-36 months (a) | 0-36 months (a) |
|---|---|---|---|---|
| Rheumatologic Physical Finding | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) | Number of Patients n(%) |
| Total with at Least One New Rheumatologic Physical Finding | 17 ( 1.7) | 24 ( 2 4) | 10 ( 1.0) | 47 ( 4.7) |
| WEAK HEADLIFT | 2 ( 0.2) | 2 ( 0.2) | 0 ( 0) | 4 ( 0.4) |
| INABILITY TO RAISE ARMS | 1 ( 0.1) | 1 ( 0.1) | 0 ( 0) | 2 ( 0.2) |
| INABILITY TO GET OUT OF CHAIR | 0 ( 0) | 1 ( 0.1) | 0 ( 0) | 1 ( 0.1) |
| WRIST SWELLING | 1 ( 0.1) | 1 ( 0.1) | 0 ( 0) | 2 ( 0.2) |
| DIGITS SWELLING | 6 ( 0.6) | 5 ( 0.5) | 2 ( 0.2) | 13 ( 1.3) |
| ELBOWS SWELLING | 0 ( 0) | 3 ( 0.3) | 0 ( 0) | 3 ( 0.3) |
| KNEES SWELLING | 2 ( 0.2) | 4 ( 0.4) | 2 ( 0.2) | 8 ( 0.8) |
| ANKLES SWELLING | 1 ( 0.1) | 4 ( 0.4) | 0 ( 0) | 5 ( 0.5) |
| BOUTONNIERE | 0 ( 0) | 1 ( 0.1) | 0 ( 0) | 1 ( 0.1) |
| TRIGGER FINGERS | 0 ( 0) | 1 ( 0.1) | 1 ( 0.1) | 2 ( 0.2) |
| JOINT TENDERNESS | 5 ( 0.5) | 11 ( 1.1) | 4 ( 0.4) | 20 ( 2.0) |
| GRIP STRENGTH AND MOTION-FINGER TO PALM CREASE | 0 ( 0) | 1 ( 0.1) | 0 ( 0) | 1 ( 0.1) |
| NECK MOTION-CHIN TO CHEST OR STERNUM | 2 ( 0.2) | 1 ( 0.1) | 0 ( 0) | 3 ( 0.3) |
| OCCIPUT TO WALL | 1 ( 0.1) | 1 ( 0.1) | 0 ( 0) | 2 ( 0.2) |
| BACK MOTION | 1 ( 0.1) | 1 ( 0.1) | 0 ( 0) | 2 ( 0.2) |
| HAIR LOSS | 2 ( 0.2) | 2 ( 0.2) | 1 ( 0.1) | 5 ( 0.5) |
| RAYNAUD'S PHENOMENON | 1 ( 0.1) | 0 ( 0) | 0 ( 0) | 1 ( 0.1) |
| SWOLLEN DIGITS | 2 ( 0.2) | 4 ( 0.4) | 0 ( 0) | 6 ( 0.6) |
| PAINLESS EYE REDNESS | 0 ( 0) | 2 ( 0.2) | 1 ( 0.1) | 3 ( 0.3) |
| TENDERNESS-INSERTION OF DELTOIDS | 0 ( 0) | 1 ( 0.1) | 0 ( 0) | 1 ( 0.1) |
| MUSCLE TENDERNESS | 0 ( 0) | 2 ( 0.2) | 0 ( 0) | 2 ( 0.2) |
| TINELS OR PHALENS SIGNS | 0 ( 0) | 1 ( 0.1) | 0 ( 0) | 1 ( 0.1) |
| SKIN RASHES | 0 ( 0) | 1 ( 0.1) | 0 ( 0) | 1 ( 0.1) |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_4.SAS

Creation Date, Time. 27JUL04 11:48

(a) Includes only rheumatologic physical findings that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.5

CUMMULATIVE INCIDENCE OF RHEUMATIC DISEASE NEWLY DIAGNOSED BY A RHEUMATOLOGIST
AUGMENTATION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Type of Diagnoses | Number with Diagnosis | Estimated Proportion with Diagnoses (b) | Number with Diagnosis | Estimated Proportion with Diagnoses (b) | Number with Diagnosis | Estimated Proportion with Diagnoses (b) |
| CONNECTIVE TISSUE DISORDERS: | | | | | | |
| SLE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SJOGREN'S SYNDROME | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SCLERODERMA | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| POLYMYOSITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OTHER CONN TISSUE DISORDERS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| INFLAMMATORY ARTHRITIS: | | | | | | |
| RHEUMATOID ARTHRITIS | 0 | 0.0000 | 1 | 0.0019 | 1 | 0.0019 |
| CRYSTALLINE ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| INFECTIOUS ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SPONDYARTHROPATHIES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OTHER INFLAMM ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NON-INFLAMMATORY RHEUMATIC CONDITIONS: | | | | | | |
| FIBROMYALGIA | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| CHRONIC FATIGUE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OTHERS: | | | | | | |
| HASHIMOTO'S THYROIDITIS | 0 | 0.0000 | 1 | 0.0019 | 1 | 0.0019 |
| HYPOTHYROIDISM | 0 | 0.0000 | 1 | 0.0019 | 1 | 0.0019 |
| PYODERMA GANGRENOSUM | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| RIGHT SHOULDER PAIN | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| Any of the Above | 0 | 0.0000 | 3 | 0.0057 | 3 | 0.0057 |
| Total Patients Assessed | 551 | | 551 | | 551 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_5.SAS

Creation Date, Time: 26JUL04 17:07

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.5

CUMMULATIVE INCIDENCE OF RHEUMATIC DISEASE NEWLY DIAGNOSED BY A RHEUMATOLOGIST
RECONSTRUCTION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Type of Diagnoses | Number with Diagnosis | Estimated Proportion with Diagnoses (b) | Number with Diagnosis | Estimated Proportion with Diagnoses (b) | Number with Diagnosis | Estimated Proportion with Diagnoses (b) |
| CONNECTIVE TISSUE DISORDERS: | | | | | | |
| SLE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SJOGREN'S SYNDROME | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SCLERODERMA | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| POLYMYOSITIS | 0 | 0 0000 | 0 | 0.0000 | 0 | 0.0000 |
| OTHER CONN TISSUE DISORDERS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| INFLAMMATORY ARTHRITIS: | | | | | | |
| RHEUMATOID ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| CRYSTALLINE ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| INFECTIOUS ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SPONDYARTHROPATHIES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OTHER INFLAMM ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NON-INFLAMMATORY RHEUMATIC CONDITIONS: | | | | | | |
| FIBROMYALGIA | 1 | 0.0042 | 1 | 0.0042 | 1 | 0.0042 |
| CHRONIC FATIGUE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OTHERS: | | | | | | |
| HASHIMOTO'S THYROIDITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| HYPOTHYROIDISM | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| PYODERMA GANGRENOSUM | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| RIGHT SHOULDER PAIN | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| Any of the Above | 1 | 0.0042 | 1 | 0.0042 | 1 | 0.0042 |
| Total Patients Assessed | 251 | | 251 | | 251 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_5.SAS
Creation Date, Time: 26JUL04 17:07
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.5

CUMMULATIVE INCIDENCE OF RHEUMATIC DISEASE NEWLY DIAGNOSED BY A RHEUMATOLOGIST
REVISION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Type of Diagnoses | Number with Diagnosis | Estimated Proportion with Diagnoses (b) | Number with Diagnosis | Estimated Proportion with Diagnoses (b) | Number with Diagnosis | Estimated Proportion with Diagnoses (b) |
| CONNECTIVE TISSUE DISORDERS: | | | | | | |
| SLE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SJOGREN'S SYNDROME | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SCLERODERMA | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| POLYMYOSITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OTHER CONN TISSUE DISORDERS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| INFLAMMATORY ARTHRITIS: | | | | | | |
| RHEUMATOID ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| CRYSTALLINE ARTHRITIS | 0 | 0.0000 | 0 | 0 0000 | 0 | 0.0000 |
| INFECTIOUS ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SPONDYARTHROPATHIES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OTHER INFLAMM ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NON-INFLAMMATORY RHEUMATIC CONDITIONS: | | | | | | |
| FIBROMYALGIA | 1 | 0.0050 | 1 | 0.0050 | 1 | 0.0050 |
| CHRONIC FATIGUE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OTHERS. | | | | | | |
| HASHIMOTO'S THYROIDITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| HYPOTHYROIDISM | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| PYODERMA GANGRENOSUM | 1 | 0.0051 | 1 | 0.0051 | 1 | 0.0051 |
| RIGHT SHOULDER PAIN | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| Any of the Above | 2 | 0.0099 | 2 | 0.0099 | 2 | 0 0099 |
| Total Patients Assessed | 205 | | 205 | | 205 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_5.SAS Creation Date, Time: 26JUL04 17:07

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.5

CUMMULATIVE INCIDENCE OF RHEUMATIC DISEASE NEWLY DIAGNOSED BY A RHEUMATOLOGIST
OVERALL PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Type of Diagnoses | Number with Diagnosis | Estimated Proportion with Diagnoses (b) | Number with Diagnosis | Estimated Proportion with Diagnoses (b) | Number with Diagnosis | Estimated Proportion with Diagnoses (b) |
| CONNECTIVE TISSUE DISORDERS: | | | | | | |
| SLE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SJOGREN'S SYNDROME | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SCLERODERMA | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| POLYMYOSITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OTHER CONN TISSUE DISORDERS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| INFLAMMATORY ARTHRITIS: | | | | | | |
| RHEUMATOID ARTHRITIS | 0 | 0.0000 | 1 | 0.0011 | 1 | 0.0011 |
| CRYSTALLINE ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| INFECTIOUS ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SPONDYARTHROPATHIES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OTHER INFLAMM ARTHRITIS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NON-INFLAMMATORY RHEUMATIC CONDITIONS: | | | | | | |
| FIBROMYALGIA | 2 | 0.0020 | 2 | 0.0020 | 2 | 0.0020 |
| CHRONIC FATIGUE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OTHERS: | | | | | | |
| HASHIMOTO'S THYROIDITIS | 0 | 0.0000 | 1 | 0.0011 | 1 | 0.0011 |
| HYPOTHYROIDISM | 0 | 0.0000 | 1 | 0.0011 | 1 | 0.0011 |
| PYODERMA GANGRENOSUM | 1 | 0.0010 | 1 | 0.0010 | 1 | 0.0010 |
| RIGHT SHOULDER PAIN | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| Any of the Above | 3 | 0.0030 | 6 | 0.0062 | 6 | 0.0062 |
| Total Patients Assessed | 1007 | | 1007 | | 1007 | |

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T11_5.SAS
Creation Date, Time: 26JUL04 17:07
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.6

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYSTEM CATEGORY
AUGMENTATION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| System Category | Number with System Category | Estimated Proportion with System Category (b) | Number with System Category | Estimated Proportion with System Category (b) | Number with System Category | Estimated Proportion with System Category (b) |
| Skin and Appendages | 2 | 0.0037 | 6 | 0.0113 | 10 | 0.0213 |
| Muscle | 6 | 0.0110 | 13 | 0.0244 | 18 | 0.0373 |
| Joint | 3 | 0.0055 | 11 | 0.0205 | 14 | 0.0285 |
| CNS | 7 | 0.0128 | 15 | 0.0279 | 20 | 0.0407 |
| Gastrointestinal | 1 | 0.0018 | 3 | 0.0056 | 4 | 0.0081 |
| Body as a Whole | 4 | 0.0073 | 14 | 0.0262 | 18 | 0.0357 |
| Metabolic and Nutritional | 0 | 0.0000 | 1 | 0.0019 | 2 | 0.0044 |
| Hearing and Vestibular | 1 | 0.0018 | 6 | 0.0115 | 7 | 0.0140 |
| Respiratory | 0 | 0.0000 | 2 | 0.0038 | 2 | 0.0038 |
| Platelet, Bleeding, Clotting Disorder | 1 | 0.0018 | 1 | 0.0018 | 2 | 0.0043 |
| Cardiovascular | 1 | 0.0018 | 1 | 0.0018 | 1 | 0.0018 |
| Vision | 2 | 0.0037 | 4 | 0.0074 | 4 | 0.0074 |
| Any of the Above | 21 | 0.0383 | 44 | 0.0821 | 51 | 0.0992 |
| Total Patients Assessed | 551 | | 551 | | 551 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_6.SAS
Creation Date, Time. 27JUL04 11:54
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.6

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYSTEM CATEGORY
RECONSTRUCTION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| System Category | Number with System Category | Estimated Proportion with System Category (b) | Number with System Category | Estimated Proportion with System Category (b) | Number with System Category | Estimated Proportion with System Category (b) |
| Skin and Appendages | 1 | 0.0040 | 1 | 0.0040 | 2 | 0.0124 |
| Muscle | 6 | 0.0249 | 12 | 0.0518 | 14 | 0.0718 |
| Joint | 9 | 0.0375 | 15 | 0.0646 | 15 | 0.0646 |
| CNS | 1 | 0.0043 | 3 | 0.0131 | 4 | 0.0214 |
| Gastrointestinal | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0084 |
| Body as a Whole | 6 | 0.0249 | 15 | 0.0712 | 17 | 0.0877 |
| Metabolic and Nutritional | 1 | 0.0043 | 1 | 0.0043 | 1 | 0.0043 |
| Hearing and Vestibular | 0 | 0.0000 | 1 | 0.0046 | 1 | 0.0046 |
| Respiratory | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| Platelet, Bleeding, Clotting Disorder | 0 | 0.0000 | 1 | 0.0047 | 1 | 0.0047 |
| Cardiovascular | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| Vision | 1 | 0.0040 | 2 | 0.0084 | 2 | 0.0084 |
| Any of the Above | 20 | 0.0825 | 36 | 0.1601 | 40 | 0.1976 |
| Total Patients Assessed | 251 | | 251 | | 251 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_6.SAS
Creation Date, Time: 27JUL04 11:54
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.6

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYSTEM CATEGORY
REVISION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| System Category | Number with System Category | Estimated Proportion with System Category (b) | Number with System Category | Estimated Proportion with System Category (b) | Number with System Category | Estimated Proportion with System Category (b) |
| Skin and Appendages | 3 | 0.0149 | 5 | 0.0255 | 8 | 0.0511 |
| Muscle | 5 | 0.0248 | 12 | 0.0619 | 15 | 0.0837 |
| Joint | 4 | 0.0198 | 10 | 0.0531 | 10 | 0.0531 |
| CNS | 5 | 0.0248 | 13 | 0.0668 | 14 | 0.0732 |
| Gastrointestinal | 2 | 0.0099 | 5 | 0.0257 | 5 | 0.0257 |
| Body as a Whole | 11 | 0.0546 | 22 | 0.1127 | 23 | 0.1200 |
| Metabolic and Nutritional | 1 | 0.0050 | 3 | 0.0156 | 3 | 0.0156 |
| Hearing and Vestibular | 3 | 0 0148 | 4 | 0.0201 | 5 | 0.0267 |
| Respiratory | 0 | 0.0000 | 1 | 0.0053 | 1 | 0.0053 |
| Platelet, Bleeding, Clotting Disorder | 1 | 0.0050 | 3 | 0.0155 | 4 | 0.0220 |
| Cardiovascular | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| Vision | 0 | 0.0000 | 2 | 0.0107 | 2 | 0.0107 |
| Any of the Above | 17 | 0.0842 | 31 | 0.1585 | 36 | 0.1982 |
| Total Patients Assessed | 205 | | 205 | | 205 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_6.SAS
Creation Date, Time: 27JUL04 11.54
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.6

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYSTEM CATEGORY
OVERALL PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| System Category | Number with System Category | Estimated Proportion with System Category (b) | Number with System Category | Estimated Proportion with System Category (b) | Number with System Category | Estimated Proportion with System Category (b) |
| Skin and Appendages | 6 | 0.0061 | 12 | 0.0126 | 20 | 0.0255 |
| Muscle | 17 | 0.0172 | 37 | 0.0387 | 47 | 0.0545 |
| Joint | 16 | 0.0162 | 36 | 0.0379 | 39 | 0 0431 |
| CNS | 13 | 0.0132 | 31 | 0.0323 | 38 | 0.0432 |
| Gastrointestinal | 3 | 0.0030 | 8 | 0.0083 | 10 | 0.0114 |
| Body as a Whole | 21 | 0.0212 | 51 | 0.0536 | 58 | 0.0639 |
| Metabolic and Nutritional | 2 | 0.0021 | 5 | 0.0053 | 6 | 0.0068 |
| Hearing and Vestibular | 4 | 0.0040 | 11 | 0.0117 | 13 | 0.0147 |
| Respiratory | 0 | 0.0000 | 3 | 0.0032 | 3 | 0.0032 |
| Platelet, Bleeding, Clotting Disorder | 2 | 0.0020 | 5 | 0.0052 | 7 | 0.0082 |
| Cardiovascular | 1 | 0.0010 | 1 | 0.0010 | 1 | 0.0010 |
| Vision | 3 | 0.0030 | 8 | 0.0083 | 8 | 0.0083 |
| Any of the Above | 58 | 0.0585 | 111 | 0.1158 | 127 | 0.1407 |
| Total Patients Assessed | 1007 | | 1007 | | 1007 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_6.SAS

Creation Date, Time: 27JUL04 11.54

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
AUGMENTATION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) |
| LOSS OF WEIGHT WITHOUT DIETING | 0 | 0.0000 | 1 | 0.0019 | 2 | 0.0044 |
| FATIGUE | 1 | 0.0018 | 7 | 0.0132 | 9 | 0.0177 |
| INSOMNIA | 2 | 0.0037 | 7 | 0.0131 | 8 | 0.0153 |
| WEAKNESS | 1 | 0.0018 | 3 | 0.0056 | 3 | 0.0056 |
| EXHAUSTION | 1 | 0.0018 | 4 | 0.0075 | 5 | 0.0100 |
| JOINT SWELLING | 1 | 0.0018 | 4 | 0.0075 | 4 | 0.0075 |
| HEEL PAIN | 1 | 0.0018 | 3 | 0.0056 | 5 | 0.0108 |
| FREQUENT MUSCLE CRAMPS | 1 | 0.0018 | 4 | 0.0075 | 5 | 0.0100 |
| NUMBNESS OF FEET | 1 | 0.0018 | 4 | 0.0075 | 5 | 0.0100 |
| RINGING IN EARS | 1 | 0.0018 | 6 | 0.0115 | 7 | 0.0140 |
| PAIN/GRITTINESS IN EYES | 2 | 0.0037 | 3 | 0.0055 | 3 | 0.0055 |
| DRYNESS OF EYES/NOSE | 0 | 0.0000 | 1 | 0.0019 | 1 | 0.0019 |
| PAIN ON SWALLOWING OR CHEWING | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NECK PAIN/STIFFNESS | 3 | 0.0055 | 6 | 0 0112 | 9 | 0.0188 |
| PAIN ON BREATHING | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| HEART MURMURS | 1 | 0.0018 | 1 | 0.0018 | 1 | 0.0018 |
| LOSS OF APPETITE | 0 | 0.0000 | 1 | 0.0019 | 1 | 0.0019 |
| PERSISTENT FEVER | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NIGHT SWEATS | 2 | 0.0036 | 5 | 0.0093 | 7 | 0.0143 |
| GENERALIZED ACHING | 0 | 0.0000 | 4 | 0.0075 | 5 | 0.0105 |
| LOSS OF HEIGHT | 0 | 0.0000 | 0 | 0.0000 | 0 | 0 0000 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_7.SAS

Creation Date, Time: 27JUL04 11:59

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
AUGMENTATION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) |
| JOINT PAIN | 2 | 0.0037 | 9 | 0.0168 | 12 | 0.0248 |
| FREQUENT MUSCLE PAIN | 0 | 0.0000 | 2 | 0.0038 | 2 | 0.0038 |
| NUMBNESS OF HANDS | 5 | 0.0091 | 10 | 0.0185 | 13 | 0.0266 |
| JAW PAIN | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OPEN SORES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| REDNESS OF EYES | 0 | 0.0000 | 1 | 0.0019 | 2 | 0.0044 |
| DRYNESS OF MOUTH | 0 | 0.0000 | 1 | 0.0019 | 1 | 0.0019 |
| BACK PAIN/STIFFNESS | 2 | 0.0036 | 6 | 0.0114 | 6 | 0.0114 |
| SEVERE CHEST PAINS | 1 | 0.0018 | 2 | 0.0037 | 2 | 0.0037 |
| CHRONIC COUGH | 0 | 0.0000 | 2 | 0.0038 | 2 | 0.0038 |
| DIFFICULTY SWALLOWING | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 1 | 0.0018 | 2 | 0.0037 | 3 | 0.0062 |
| SEVERE RASHES | 1 | 0.0018 | 3 | 0.0056 | 3 | 0.0056 |
| SEVERE DRYNESS OF SKIN | 1 | 0.0018 | 1 | 0.0018 | 3 | 0.0068 |
| TENDER LUMPS/BUMPS | 0 | 0.0000 | 1 | 0.0019 | 1 | 0.0019 |
| EXCESSIVE SENSITIVITY TO SUN | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| FREQUENT HIVES | 0 | 0.0000 | 1 | 0.0020 | 1 | 0.0020 |
| TIGHTNESS OF SKIN | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| UNUSUAL HAIR LOSS | 0 | 0.0000 | 1 | 0.0019 | 3 | 0.0069 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_7.SAS
Creation Date, Time: 27JUL04 11:59

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
AUGMENTATION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) |
| TENDERNESS OF SCALP | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | 1 | 0.0018 | 1 | 0.0018 | 2 | 0.0043 |
| Any of the Above | 21 | 0.0383 | 44 | 0 0821 | 51 | 0.0992 |
| Total Patients Assessed | 551 | | 551 | | 551 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_7.SAS
Creation Date, Time: 27JUL04 11:59
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
RECONSTRUCTION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) |
| LOSS OF WEIGHT WITHOUT DIETING | 1 | 0.0043 | 1 | 0.0043 | 1 | 0.0043 |
| FATIGUE | 2 | 0.0083 | 6 | 0.0286 | 7 | 0.0371 |
| INSOMNIA | 1 | 0.0043 | 3 | 0.0131 | 4 | 0.0214 |
| WEAKNESS | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0084 |
| EXHAUSTION | 0 | 0.0000 | 2 | 0.0090 | 2 | 0.0090 |
| JOINT SWELLING | 2 | 0.0085 | 5 | 0.0227 | 5 | 0.0227 |
| HEEL PAIN | 0 | 0.0000 | 1 | 0.0046 | 2 | 0.0130 |
| FREQUENT MUSCLE CRAMPS | 3 | 0.0125 | 8 | 0.0351 | 8 | 0.0351 |
| NUMBNESS OF FEET | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| RINGING IN EARS | 0 | 0.0000 | 1 | 0.0046 | 1 | 0.0046 |
| PAIN/GRITTINESS IN EYES | 1 | 0.0040 | 2 | 0.0084 | 2 | 0.0084 |
| DRYNESS OF EYES/NOSE | 1 | 0.0040 | 2 | 0.0084 | 2 | 0.0084 |
| PAIN ON SWALLOWING OR CHEWING | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NECK PAIN/STIFFNESS | 0 | 0.0000 | 2 | 0.0090 | 4 | 0.0299 |
| PAIN ON BREATHING | 0 | 0.0000 | 0 | 0.0000 | 0 | 0 0000 |
| HEART MURMURS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| LOSS OF APPETITE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| PERSISTENT FEVER | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NIGHT SWEATS | 2 | 0.0084 | 4 | 0.0194 | 5 | 0.0277 |
| GENERALIZED ACHING | 1 | 0.0042 | 3 | 0.0130 | 3 | 0.0130 |
| LOSS OF HEIGHT | 2 | 0.0085 | 4 | 0.0175 | 4 | 0.0175 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_7.SAS

Creation Date, Time: 27JUL04 11.59

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
RECONSTRUCTION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) |
| JOINT PAIN | 9 | 0.0375 | 14 | 0.0602 | 14 | 0.0602 |
| FREQUENT MUSCLE PAIN | 2 | 0.0084 | 3 | 0.0128 | 3 | 0.0128 |
| NUMBNESS OF HANDS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| JAW PAIN | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0084 |
| OPEN SORES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| REDNESS OF EYES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| DRYNESS OF MOUTH | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| BACK PAIN/STIFFNESS | 2 | 0.0083 | 3 | 0.0127 | 3 | 0.0127 |
| SEVERE CHEST PAINS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| CHRONIC COUGH | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| DIFFICULTY SWALLOWING | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0084 |
| SEVERE RASHES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SEVERE DRYNESS OF SKIN | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TENDER LUMPS/BUMPS | 0 | 0.0000 | 1 | 0.0068 | 1 | 0.0068 |
| EXCESSIVE SENSITIVITY TO SUN | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| FREQUENT HIVES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TIGHTNESS OF SKIN | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| UNUSUAL HAIR LOSS | 1 | 0.0040 | 1 | 0.0040 | 2 | 0.0124 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_7.SAS

Creation Date, Time: 27JUL04 11:59

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
RECONSTRUCTION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) |
| TENDERNESS OF SCALP | 1 | 0.0043 | 1 | 0.0043 | 1 | 0.0043 |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | 0 | 0.0000 | 1 | 0.0047 | 1 | 0.0047 |
| Any of the Above | 20 | 0.0825 | 36 | 0.1601 | 40 | 0.1976 |
| Total Patients Assessed | 251 | | 251 | | 251 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_7.SAS
Creation Date, Time. 27JUL04 11:59
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
REVISION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) |
| LOSS OF WEIGHT WITHOUT DIETING | 1 | 0.0050 | 3 | 0.0156 | 3 | 0.0156 |
| FATIGUE | 5 | 0.0249 | 9 | 0.0460 | 11 | 0.0595 |
| INSOMNIA | 2 | 0.0099 | 5 | 0.0258 | 5 | 0.0258 |
| WEAKNESS | 1 | 0.0050 | 4 | 0.0209 | 5 | 0.0275 |
| EXHAUSTION | 1 | 0.0050 | 5 | 0.0262 | 6 | 0.0327 |
| JOINT SWELLING | 0 | 0.0000 | 3 | 0.0164 | 4 | 0.0229 |
| HEEL PAIN | 2 | 0.0099 | 2 | 0.0099 | 2 | 0.0099 |
| FREQUENT MUSCLE CRAMPS | 1 | 0.0050 | 4 | 0.0206 | 5 | 0.0278 |
| NUMBNESS OF FEET | 2 | 0.0099 | 3 | 0.0160 | 4 | 0.0225 |
| RINGING IN EARS | 3 | 0.0148 | 4 | 0.0201 | 5 | 0.0267 |
| PAIN/GRITTINESS IN EYES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| DRYNESS OF EYES/NOSE | 1 | 0.0050 | 2 | 0.0102 | 2 | 0.0102 |
| PAIN ON SWALLOWING OR CHEWING | 0 | 0.0000 | 2 | 0.0107 | 2 | 0.0107 |
| NECK PAIN/STIFFNESS | 3 | 0.0149 | 4 | 0.0202 | 4 | 0.0202 |
| PAIN ON BREATHING | 0 | 0.0000 | 1 | 0.0053 | 1 | 0.0053 |
| HEART MURMURS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| LOSS OF APPETITE | 0 | 0.0000 | 2 | 0.0106 | 2 | 0.0106 |
| PERSISTENT FEVER | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NIGHT SWEATS | 3 | 0.0148 | 4 | 0.0200 | 4 | 0.0200 |
| GENERALIZED ACHING | 2 | 0.0099 | 6 | 0.0321 | 7 | 0.0387 |
| LOSS OF HEIGHT | 0 | 0.0000 | 1 | 0.0053 | 1 | 0.0053 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_7.SAS
Creation Date, Time: 27JUL04 11:59
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
REVISION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) |
| JOINT PAIN | 4 | 0.0198 | 10 | 0.0531 | 10 | 0.0531 |
| FREQUENT MUSCLE PAIN | 2 | 0.0099 | 2 | 0.0099 | 2 | 0.0099 |
| NUMBNESS OF HANDS | 1 | 0.0050 | 7 | 0.0366 | 8 | 0.0431 |
| JAW PAIN | 1 | 0.0050 | 1 | 0.0050 | 1 | 0.0050 |
| OPEN SORES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| REDNESS OF EYES | 0 | 0.0000 | 2 | 0.0107 | 2 | 0.0107 |
| DRYNESS OF MOUTH | 1 | 0.0050 | 2 | 0.0103 | 2 | 0.0103 |
| BACK PAIN/STIFFNESS | 2 | 0.0099 | 6 | 0.0321 | 8 | 0.0469 |
| SEVERE CHEST PAINS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| CHRONIC COUGH | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| DIFFICULTY SWALLOWING | 0 | 0.0000 | 2 | 0.0107 | 2 | 0.0107 |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 2 | 0.0099 | 4 | 0.0204 | 4 | 0.0204 |
| SEVERE RASHES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SEVERE DRYNESS OF SKIN | 1 | 0.0050 | 3 | 0.0156 | 5 | 0.0328 |
| TENDER LUMPS/BUMPS | 2 | 0.0099 | 4 | 0.0203 | 5 | 0.0269 |
| EXCESSIVE SENSITIVITY TO SUN | 1 | 0.0050 | 1 | 0.0050 | 1 | 0.0050 |
| COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE | 1 | 0.0050 | 2 | 0.0101 | 2 | 0.0101 |
| FREQUENT HIVES | 1 | 0.0049 | 1 | 0.0049 | 1 | 0.0049 |
| TIGHTNESS OF SKIN | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| UNUSUAL HAIR LOSS | 1 | 0.0051 | 2 | 0.0103 | 3 | 0.0188 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_7.SAS

Creation Date, Time: 27JUL04 11.59

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
REVISION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) |
| TENDERNESS OF SCALP | 1 | 0.0049 | 1 | 0.0049 | 1 | 0.0049 |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | 1 | 0.0050 | 3 | 0.0155 | 4 | 0.0220 |
| Any of the Above | 17 | 0.0842 | 31 | 0.1585 | 36 | 0.1982 |
| Total Patients Assessed | 205 | | 205 | | 205 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_7.SAS
Creation Date, Time: 27JUL04 11:59
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
OVERALL PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) |
| LOSS OF WEIGHT WITHOUT DIETING | 2 | 0.0021 | 5 | 0.0053 | 6 | 0.0068 |
| FATIGUE | 8 | 0.0081 | 22 | 0.0232 | 27 | 0.0304 |
| INSOMNIA | 5 | 0.0051 | 15 | 0.0158 | 17 | 0.0186 |
| WEAKNESS | 2 | 0.0020 | 7 | 0.0074 | 9 | 0.0103 |
| EXHAUSTION | 2 | 0.0020 | 11 | 0.0116 | 13 | 0.0146 |
| JOINT SWELLING | 3 | 0.0030 | 12 | 0.0128 | 13 | 0.0142 |
| HEEL PAIN | 3 | 0.0030 | 6 | 0.0062 | 9 | 0.0109 |
| FREQUENT MUSCLE CRAMPS | 5 | 0.0051 | 16 | 0.0167 | 18 | 0.0198 |
| NUMBNESS OF FEET | 3 | 0.0030 | 7 | 0.0076 | 9 | 0.0105 |
| RINGING IN EARS | 4 | 0.0040 | 11 | 0.0117 | 13 | 0.0147 |
| PAIN/GRITTINESS IN EYES | 3 | 0.0030 | 5 | 0.0051 | 5 | 0.0051 |
| DRYNESS OF EYES/NOSE | 2 | 0.0020 | 5 | 0.0052 | 5 | 0.0052 |
| PAIN ON SWALLOWING OR CHEWING | 0 | 0.0000 | 2 | 0.0022 | 2 | 0.0022 |
| NECK PAIN/STIFFNESS | 6 | 0.0061 | 12 | 0.0125 | 17 | 0.0206 |
| PAIN ON BREATHING | 0 | 0.0000 | 1 | 0.0011 | 1 | 0.0011 |
| HEART MURMURS | 1 | 0.0010 | 1 | 0.0010 | 1 | 0.0010 |
| LOSS OF APPETITE | 0 | 0.0000 | 3 | 0.0032 | 3 | 0.0032 |
| PERSISTENT FEVER | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NIGHT SWEATS | 7 | 0.0070 | 13 | 0.0136 | 16 | 0.0181 |
| GENERALIZED ACHING | 3 | 0.0030 | 13 | 0.0140 | 15 | 0.0174 |
| LOSS OF HEIGHT | 2 | 0.0021 | 5 | 0.0052 | 5 | 0.0052 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_7.SAS
Creation Date, Time: 27JUL04 11.59
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
OVERALL PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) |
| JOINT PAIN | 15 | 0.0152 | 33 | 0.0348 | 36 | 0.0400 |
| FREQUENT MUSCLE PAIN | 4 | 0.0040 | 7 | 0.0072 | 7 | 0.0072 |
| NUMBNESS OF HANDS | 6 | 0.0060 | 17 | 0.0178 | 21 | 0.0243 |
| JAW PAIN | 1 | 0.0010 | 1 | 0.0010 | 2 | 0.0025 |
| OPEN SORES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| REDNESS OF EYES | 0 | 0.0000 | 3 | 0.0032 | 4 | 0.0047 |
| DRYNESS OF MOUTH | 1 | 0.0010 | 3 | 0.0032 | 3 | 0.0032 |
| BACK PAIN/STIFFNESS | 6 | 0.0060 | 15 | 0.0161 | 17 | 0.0192 |
| SEVERE CHEST PAINS | 1 | 0.0010 | 2 | 0.0021 | 2 | 0.0021 |
| CHRONIC COUGH | 0 | 0.0000 | 2 | 0.0021 | 2 | 0.0021 |
| DIFFICULTY SWALLOWING | 0 | 0.0000 | 2 | 0.0022 | 2 | 0.0022 |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 3 | 0.0030 | 6 | 0.0062 | 8 | 0.0092 |
| SEVERE RASHES | 1 | 0.0010 | 3 | 0.0032 | 3 | 0.0032 |
| SEVERE DRYNESS OF SKIN | 2 | 0.0020 | 4 | 0.0042 | 8 | 0.0107 |
| TENDER LUMPS/BUMPS | 2 | 0.0020 | 6 | 0.0065 | 7 | 0.0079 |
| EXCESSIVE SENSITIVITY TO SUN | 1 | 0.0010 | 1 | 0.0010 | 1 | 0.0010 |
| COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE | 1 | 0.0010 | 2 | 0.0020 | 2 | 0.0020 |
| FREQUENT HIVES | 1 | 0.0010 | 2 | 0.0022 | 2 | 0.0022 |
| TIGHTNESS OF SKIN | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| UNUSUAL HAIR LOSS | 2 | 0.0020 | 4 | 0.0042 | 8 | 0.0105 |

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T11_7.SAS
Creation Date, Time: 27JUL04 11:59
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
OVERALL PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) |
| TENDERNESS OF SCALP | 2 | 0.0020 | 2 | 0.0020 | 2 | 0.0020 |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | 2 | 0.0020 | 5 | 0.0052 | 7 | 0.0082 |
| Any of the Above | 58 | 0.0585 | 111 | 0.1158 | 127 | 0 1407 |
| Total Patients Assessed | 1007 | | 1007 | | 1007 | |

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_7.SAS
Creation Date, Time: 27JUL04 11:59
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.8

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE RHEUMATOLOGIC PHYSICAL EXAMINATION FINDINGS
AUGMENTATION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Examination Findings | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) |
| WEAK HEADLIFT | 1 | 0.0018 | 1 | 0.0018 | 1 | 0.0018 |
| INABILITY TO RAISE ARMS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| INABILITY TO GET OUT OF CHAIR | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| WRIST SWELLING | 1 | 0.0018 | 1 | 0.0018 | 1 | 0.0018 |
| DIGITS SWELLING | 2 | 0.0037 | 3 | 0.0055 | 4 | 0.0085 |
| ELBOWS SWELLING | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| KNEES SWELLING | 1 | 0.0019 | 1 | 0.0019 | 2 | 0.0048 |
| ANKLES SWELLING | 0 | 0.0000 | 1 | 0.0019 | 1 | 0.0019 |
| BOUTONNIERE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| ULNAR DRIFT | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SWAN NECK | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TRIGGER FINGERS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| JOINT TENDERNESS | 1 | 0.0018 | 4 | 0.0075 | 7 | 0.0147 |
| GRIP STRENGTH AND MOTION-FINGER TO PALM CREASE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NECK MOTION-CHIN TO CHEST OR STERNUM | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| CHEST EXPANSION | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OCCIPUT TO WALL | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| JAW MOTION | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| BACK MOTION | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| HAIR LOSS | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_8.SAS

Creation Date, Time: 26JUL04 17:10

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.8

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE RHEUMATOLOGIC PHYSICAL EXAMINATION FINDINGS
AUGMENTATION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Examination Findings | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) |
| SKIN TIGHTNESS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| RAYNAUD'S PHENOMENON | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| CALCINOSIS OVER TIBIA,ULNA,ELBOWS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SWOLLEN DIGITS | 0 | 0.0000 | 1 | 0.0019 | 1 | 0.0019 |
| ERYTHEMA OVER KNUCKLES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| BLUISH HUE COLOR ON EYELIDS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NON-TENDER LUMPS OR BUMPS ON ELBOWS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TENDER LUMPS-TIBIA | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| PAINLESS EYE REDNESS | 0 | 0.0000 | 2 | 0.0038 | 3 | 0.0063 |
| PAINFUL EYE REDNESS WITH DECREASED VISION,SMALL PUPILS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TENDERNESS-INSERTION OF DELTOIDS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| MUSCLE TENDERNESS | 0 | 0.0000 | 1 | 0.0019 | 1 | 0.0019 |
| NAIL PITTINGS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TINELS OR PHALENS SIGNS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SKIN RASHES | 0 | 0.0000 | 1 | 0.0019 | 1 | 0.0019 |
| Any of the Above | 5 | 0.0092 | 12 | 0.0224 | 16 | 0.0322 |
| Total Patients Assessed | 551 | | 551 | | 551 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_8.SAS

Creation Date, Time. 26JUL04 17.10

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.8

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE RHEUMATOLOGIC PHYSICAL EXAMINATION FINDINGS
RECONSTRUCTION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Examination Findings | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) |
| WEAK HEADLIFT | 0 | 0.0000 | 2 | 0.0091 | 2 | 0.0091 |
| INABILITY TO RAISE ARMS | 0 | 0.0000 | 1 | 0.0047 | 1 | 0.0047 |
| INABILITY TO GET OUT OF CHAIR | 0 | 0.0000 | 1 | 0.0047 | 1 | 0.0047 |
| WRIST SWELLING | 0 | 0.0000 | 1 | 0.0075 | 1 | 0.0075 |
| DIGITS SWELLING | 3 | 0.0126 | 5 | 0.0217 | 5 | 0.0217 |
| ELBOWS SWELLING | 0 | 0.0000 | 2 | 0.0090 | 2 | 0.0090 |
| KNEES SWELLING | 1 | 0.0042 | 3 | 0.0140 | 3 | 0.0140 |
| ANKLES SWELLING | 1 | 0.0042 | 3 | 0.0132 | 3 | 0.0132 |
| BOUTONNIERE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| ULNAR DRIFT | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SWAN NECK | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TRIGGER FINGERS | 0 | 0.0000 | 1 | 0.0044 | 1 | 0.0044 |
| JOINT TENDERNESS | 1 | 0.0041 | 4 | 0.0203 | 5 | 0.0279 |
| GRIP STRENGTH AND MOTION-FINGER TO PALM CREASE | 0 | 0.0000 | 1 | 0.0047 | 1 | 0.0047 |
| NECK MOTION-CHIN TO CHEST OR STERNUM | 1 | 0.0042 | 2 | 0.0088 | 2 | 0.0088 |
| CHEST EXPANSION | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OCCIPUT TO WALL | 1 | 0.0043 | 2 | 0.0089 | 2 | 0.0089 |
| JAW MOTION | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| BACK MOTION | 0 | 0.0000 | 1 | 0.0047 | 1 | 0.0047 |
| HAIR LOSS | 0 | 0.0000 | 1 | 0.0050 | 1 | 0.0050 |

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T11_8.SAS

Creation Date, Time: 26JUL04 17:10

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.8

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE RHEUMATOLOGIC PHYSICAL EXAMINATION FINDINGS
RECONSTRUCTION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Examination Findings | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) |
| SKIN TIGHTNESS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| RAYNAUD'S PHENOMENON | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| CALCINOSIS OVER TIBIA,ULNA,ELBOWS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SWOLLEN DIGITS | 2 | 0.0084 | 4 | 0.0178 | 4 | 0.0178 |
| ERYTHEMA OVER KNUCKLES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| BLUISH HUE COLOR ON EYELIDS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NON-TENDER LUMPS OR BUMPS ON ELBOWS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TENDER LUMPS-TIBIA | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| PAINLESS EYE REDNESS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| PAINFUL EYE REDNESS WITH DECREASED VISION,SMALL PUPILS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TENDERNESS-INSERTION OF DELTOIDS | 0 | 0.0000 | 1 | 0.0047 | 1 | 0.0047 |
| MUSCLE TENDERNESS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NAIL PITTINGS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TINELS OR PHALENS SIGNS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SKIN RASHES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| Any of the Above | 5 | 0.0209 | 12 | 0.0533 | 13 | 0.0611 |
| Total Patients Assessed | 251 | | 251 | | 251 | |

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T11_8.SAS Creation Date, Time: 26JUL04 17:10

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.8

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE RHEUMATOLOGIC PHYSICAL EXAMINATION FINDINGS
REVISION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Examination Findings | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) |
| WEAK HEADLIFT | 1 | 0.0050 | 1 | 0.0050 | 1 | 0.0050 |
| INABILITY TO RAISE ARMS | 1 | 0.0050 | 1 | 0.0050 | 1 | 0.0050 |
| INABILITY TO GET OUT OF CHAIR | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| WRIST SWELLING | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| DIGITS SWELLING | 1 | 0.0049 | 3 | 0.0162 | 4 | 0.0227 |
| ELBOWS SWELLING | 0 | 0.0000 | 1 | 0.0053 | 1 | 0.0053 |
| KNEES SWELLING | 0 | 0.0000 | 2 | 0.0106 | 3 | 0.0179 |
| ANKLES SWELLING | 0 | 0.0000 | 1 | 0.0054 | 1 | 0.0054 |
| BOUTONNIERE | 0 | 0.0000 | 1 | 0.0052 | 1 | 0.0052 |
| ULNAR DRIFT | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SWAN NECK | 0 | 0.0000 | 0 | 0.0000 | 0 | 0 0000 |
| TRIGGER FINGERS | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0074 |
| JOINT TENDERNESS | 3 | 0.0148 | 8 | 0.0416 | 8 | 0.0416 |
| GRIP STRENGTH AND MOTION-FINGER TO PALM CREASE | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NECK MOTION-CHIN TO CHEST OR STERNUM | 1 | 0.0050 | 1 | 0.0050 | 1 | 0.0050 |
| CHEST EXPANSION | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OCCIPUT TO WALL | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| JAW MOTION | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| BACK MOTION | 1 | 0.0050 | 1 | 0.0050 | 1 | 0.0050 |
| HAIR LOSS | 2 | 0 0100 | 3 | 0.0152 | 3 | 0.0152 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_8.SAS Creation Date, Time: 26JUL04 17:10

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.8

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE RHEUMATOLOGIC PHYSICAL EXAMINATION FINDINGS
REVISION PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Examination Findings | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) |
| SKIN TIGHTNESS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| RAYNAUD'S PHENOMENON | 1 | 0.0050 | 1 | 0.0050 | 1 | 0.0050 |
| CALCINOSIS OVER TIBIA,ULNA,ELBOWS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SWOLLEN DIGITS | 0 | 0.0000 | 1 | 0.0053 | 1 | 0.0053 |
| ERYTHEMA OVER KNUCKLES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| BLUISH HUE COLOR ON EYELIDS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NON-TENDER LUMPS OR BUMPS ON ELBOWS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TENDER LUMPS-TIBIA | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| PAINLESS EYE REDNESS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| PAINFUL EYE REDNESS WITH DECREASED VISION,SMALL PUPILS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TENDERNESS-INSERTION OF DELTOIDS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| MUSCLE TENDERNESS | 0 | 0.0000 | 1 | 0.0053 | 1 | 0.0053 |
| NAIL PITTINGS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TINELS OR PHALENS SIGNS | 0 | 0.0000 | 1 | 0.0051 | 1 | 0.0051 |
| SKIN RASHES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| Any of the Above | 7 | 0.0347 | 16 | 0.0825 | 18 | 0.0970 |
| Total Patients Assessed | 205 | | 205 | | 205 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_8.SAS
Creation Date, Time: 26JUL04 17:10
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.8

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE RHEUMATOLOGIC PHYSICAL EXAMINATION FINDINGS
OVERALL PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Examination Findings | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) |
| WEAK HEADLIFT | 2 | 0.0020 | 4 | 0.0042 | 4 | 0.0042 |
| INABILITY TO RAISE ARMS | 1 | 0.0010 | 2 | 0.0021 | 2 | 0.0021 |
| INABILITY TO GET OUT OF CHAIR | 0 | 0.0000 | 1 | 0.0011 | 1 | 0.0011 |
| WRIST SWELLING | 1 | 0 0010 | 2 | 0.0023 | 2 | 0.0023 |
| DIGITS SWELLING | 6 | 0.0061 | 11 | 0.0116 | 13 | 0.0150 |
| ELBOWS SWELLING | 0 | 0.0000 | 3 | 0.0032 | 3 | 0.0032 |
| KNEES SWELLING | 2 | 0.0020 | 6 | 0.0064 | 8 | 0.0099 |
| ANKLES SWELLING | 1 | 0.0010 | 5 | 0.0053 | 5 | 0.0053 |
| BOUTONNIERE | 0 | 0.0000 | 1 | 0.0011 | 1 | 0.0011 |
| ULNAR DRIFT | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SWAN NECK | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TRIGGER FINGERS | 0 | 0.0000 | 1 | 0.0011 | 2 | 0.0026 |
| JOINT TENDERNESS | 5 | 0.0050 | 16 | 0.0171 | 20 | 0.0228 |
| GRIP STRENGTH AND MOTION-FINGER TO PALM CREASE | 0 | 0.0000 | 1 | 0.0011 | 1 | 0.0011 |
| NECK MOTION-CHIN TO CHEST OR STERNUM | 2 | 0.0020 | 3 | 0.0031 | 3 | 0.0031 |
| CHEST EXPANSION | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| OCCIPUT TO WALL | 1 | 0.0010 | 2 | 0.0021 | 2 | 0.0021 |
| JAW MOTION | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| BACK MOTION | 1 | 0.0010 | 2 | 0.0021 | 2 | 0.0021 |
| HAIR LOSS | 2 | 0.0020 | 4 | 0.0042 | 5 | 0.0057 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_8.SAS

Creation Date, Time: 26JUL04 17:10

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.8

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE RHEUMATOLOGIC PHYSICAL EXAMINATION FINDINGS
OVERALL PATIENTS

| | Time from Implant Surgery (a) | | | | | |
|---|---|---|---|---|---|---|
| | 12 months | | 24 months | | 36 months | |
| Examination Findings | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) | Number with Examination Findings | Estimated Proportion with Examination Findings (b) |
| SKIN TIGHTNESS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| RAYNAUD'S PHENOMENON | 1 | 0.0010 | 1 | 0.0010 | 1 | 0.0010 |
| CALCINOSIS OVER TIBIA,ULNA,ELBOWS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| SWOLLEN DIGITS | 2 | 0.0020 | 6 | 0.0063 | 6 | 0.0063 |
| ERYTHEMA OVER KNUCKLES | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| BLUISH HUE COLOR ON EYELIDS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| NON-TENDER LUMPS OR BUMPS ON ELBOWS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TENDER LUMPS-TIBIA | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| PAINLESS EYE REDNESS | 0 | 0.0000 | 2 | 0.0021 | 3 | 0.0036 |
| PAINFUL EYE REDNESS WITH DECREASED VISION,SMALL PUPILS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TENDERNESS-INSERTION OF DELTOIDS | 0 | 0.0000 | 1 | 0.0011 | 1 | 0.0011 |
| MUSCLE TENDERNESS | 0 | 0.0000 | 2 | 0.0021 | 2 | 0.0021 |
| NAIL PITTINGS | 0 | 0.0000 | 0 | 0.0000 | 0 | 0.0000 |
| TINELS OR PHALENS SIGNS | 0 | 0.0000 | 1 | 0.0010 | 1 | 0.0010 |
| SKIN RASHES | 0 | 0.0000 | 1 | 0.0011 | 1 | 0.0011 |
| Any of the Above | 17 | 0 0172 | 40 | 0.0419 | 47 | 0.0523 |
| Total Patients Assessed | 1007 | | 1007 | | 1007 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_8.SAS
Creation Date, Time: 26JUL04 17:10

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.9

INCIDENCE OF PATIENT REPORT OF POSTOPERATIVE RHEUMATOLOGICAL SYMPTOMS - FDA Item 8

| | | 12 Months | | 24 Months | | 36 Months | |
|---|---|---|---|---|---|---|---|
| Symptom Type | Baseline | Yes | No | Yes | No | Yes | No |
| LOSS OF WEIGHT WITHOUT DIETING | Yes | 1 | 3 | 1 | 3 | 0 | 2 |
| | No | 0 | 835 | 2 | 798 | 1 | 574 |
| FATIGUE | Yes | 7 | 5 | 5 | 4 | 1 | 1 |
| | No | 6 | 835 | 14 | 798 | 6 | 574 |
| INSOMNIA | Yes | 12 | 18 | 8 | 20 | 2 | 13 |
| | No | 4 | 835 | 9 | 798 | 2 | 574 |
| WEAKNESS | Yes | 1 | 0 | 1 | 0 | 0 | 0 |
| | No | 2 | 835 | 6 | 798 | 2 | 574 |
| EXHAUSTION | Yes | 1 | 0 | 1 | 0 | 0 | 0 |
| | No | 1 | 835 | 9 | 798 | 3 | 574 |
| JOINT SWELLING | Yes | 4 | 4 | 4 | 4 | 0 | 2 |
| | No | 3 | 835 | 7 | 798 | 4 | 574 |
| HEEL PAIN | Yes | 2 | 1 | 0 | 2 | 1 | 0 |
| | No | 2 | 835 | 6 | 798 | 2 | 574 |
| FREQUENT MUSCLE CRAMPS | Yes | 2 | 2 | 2 | 2 | 0 | 1 |
| | No | 4 | 835 | 9 | 798 | 4 | 574 |
| NUMBNESS OF FEET | Yes | 1 | 2 | 1 | 2 | 0 | 1 |
| | No | 1 | 835 | 7 | 798 | 2 | 574 |
| RINGING IN EARS | Yes | 6 | 8 | 4 | 9 | 2 | 5 |

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.9

INCIDENCE OF PATIENT REPORT OF POSTOPERATIVE RHEUMATOLOGICAL SYMPTOMS - FDA Item 8

| | | 12 Months | | 24 Months | | 36 Months | |
|---|---|---|---|---|---|---|---|
| Symptom Type | Baseline | Yes | No | Yes | No | Yes | No |
| RINGING IN EARS | No | 3 | 835 | 7 | 798 | 4 | 574 |
| PAIN/GRITTINESS IN EYES | No | 2 | 835 | 2 | 798 | 1 | 574 |
| DRYNESS OF EYES/NOSE | Yes | 9 | 8 | 8 | 8 | 2 | 8 |
| | No | 0 | 835 | 1 | 798 | 1 | 574 |
| PAIN ON SWALLOWING OR CHEWING | Yes | 1 | 0 | 1 | 0 | 0 | 0 |
| | No | 0 | 835 | 2 | 798 | 0 | 574 |
| NECK PAIN/STIFFNESS | Yes | 9 | 12 | 6 | 12 | 3 | 12 |
| | No | 4 | 835 | 6 | 798 | 6 | 574 |
| PAIN ON BREATHING | No | 0 | 835 | 1 | 798 | 0 | 574 |
| HEART MURMURS | Yes | 15 | 22 | 13 | 22 | 3 | 17 |
| | No | 1 | 835 | 1 | 798 | 1 | 574 |
| LOSS OF APPETITE | Yes | 1 | 0 | 1 | 0 | 0 | 0 |
| | No | 0 | 835 | 3 | 798 | 0 | 574 |
| PERSISTENT FEVER | No | 0 | 835 | 0 | 798 | 0 | 574 |
| NIGHT SWEATS | Yes | 8 | 13 | 6 | 13 | 1 | 6 |
| | No | 5 | 835 | 6 | 798 | 4 | 574 |
| GENERALIZED ACHING | Yes | 5 | 4 | 6 | 4 | 1 | 3 |
| | No | 1 | 835 | 8 | 798 | 4 | 574 |

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.9

INCIDENCE OF PATIENT REPORT OF POSTOPERATIVE RHEUMATOLOGICAL SYMPTOMS - FDA Item 8

| | | 12 Months | | 24 Months | | 36 Months | |
|---|---|---|---|---|---|---|---|
| Symptom Type | Baseline | Yes | No | Yes | No | Yes | No |
| LOSS OF HEIGHT | Yes | 2 | 2 | 2 | 2 | 0 | 1 |
| | No | 0 | 835 | 2 | 798 | 0 | 574 |
| JOINT PAIN | Yes | 9 | 9 | 9 | 9 | 2 | 4 |
| | No | 9 | 835 | 18 | 798 | 12 | 574 |
| FREQUENT MUSCLE PAIN | Yes | 4 | 3 | 2 | 2 | 0 | 3 |
| | No | 3 | 835 | 5 | 798 | 1 | 574 |
| NUMBNESS OF HANDS | Yes | 4 | 7 | 3 | 8 | 4 | 6 |
| | No | 4 | 835 | 12 | 798 | 5 | 574 |
| JAW PAIN | Yes | 3 | 4 | 3 | 4 | 1 | 3 |
| | No | 0 | 835 | 0 | 798 | 0 | 574 |
| OPEN SORES | No | 0 | 835 | 0 | 798 | 0 | 574 |
| REDNESS OF EYES | Yes | 3 | 0 | 3 | 0 | 1 | 1 |
| | No | 0 | 835 | 1 | 798 | 1 | 574 |
| DRYNESS OF MOUTH | Yes | 1 | 3 | 1 | 2 | 1 | 2 |
| | No | 1 | 835 | 2 | 798 | 2 | 574 |
| BACK PAIN/STIFFNESS | Yes | 11 | 13 | 10 | 12 | 2 | 9 |
| | No | 5 | 835 | 12 | 798 | 4 | 574 |
| SEVERE CHEST PAINS | No | 1 | 835 | 2 | 798 | 0 | 574 |

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11 9

INCIDENCE OF PATIENT REPORT OF POSTOPERATIVE RHEUMATOLOGICAL SYMPTOMS - FDA Item 8

| | | 12 Months | | 24 Months | | 36 Months | |
|---|---|---|---|---|---|---|---|
| Symptom Type | Baseline | Yes | No | Yes | No | Yes | No |
| CHRONIC COUGH | Yes | 0 | 1 | 0 | 1 | 0 | 1 |
| | No | 0 | 835 | 2 | 798 | 0 | 574 |
| DIFFICULTY SWALLOWING | No | 0 | 835 | 2 | 798 | 0 | 574 |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | Yes | 4 | 5 | 4 | 5 | 2 | 4 |
| | No | 2 | 835 | 2 | 798 | 2 | 574 |
| SEVERE RASHES | No | 1 | 835 | 2 | 798 | 0 | 574 |
| SEVERE DRYNESS OF SKIN | Yes | 1 | 1 | 2 | 1 | 1 | 0 |
| | No | 3 | 835 | 1 | 798 | 2 | 574 |
| TENDER LUMPS/BUMPS | Yes | 1 | 1 | 1 | 1 | 0 | 0 |
| | No | 1 | 835 | 4 | 798 | 1 | 574 |
| EXCESSIVE SENSITIVITY TO SUN | Yes | 2 | 1 | 2 | 1 | 2 | 1 |
| | No | 0 | 835 | 1 | 798 | 0 | 574 |
| COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE | Yes | 8 | 9 | 8 | 9 | 6 | 8 |
| | No | 1 | 835 | 1 | 798 | 1 | 574 |
| FREQUENT HIVES | Yes | 0 | 1 | 0 | 0 | 0 | 0 |
| | No | 0 | 835 | 1 | 798 | 0 | 574 |
| TIGHTNESS OF SKIN | Yes | 0 | 1 | 0 | 1 | 0 | 0 |
| | No | 0 | 835 | 0 | 798 | 0 | 574 |

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.9

INCIDENCE OF PATIENT REPORT OF POSTOPERATIVE RHEUMATOLOGICAL SYMPTOMS - FDA Item 8

| Symptom Type | Baseline | 12 Months | | 24 Months | | 36 Months | |
|---|---|---|---|---|---|---|---|
| | | Yes | No | Yes | No | Yes | No |
| UNUSUAL HAIR LOSS | Yes | 3 | 3 | 3 | 3 | 1 | 2 |
| | No | 1 | 835 | 1 | 798 | 4 | 574 |
| TENDERNESS OF SCALP | Yes | 0 | 1 | 0 | 1 | 0 | 1 |
| | No | 0 | 835 | 0 | 798 | 0 | 574 |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | Yes | 4 | 5 | 4 | 7 | 1 | 3 |
| | No | 2 | 835 | 3 | 798 | 3 | 574 |

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.10

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYSTEM CATEGORY
AUGMENTATION PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery (a) | | | | |
|---|---|---|---|---|---|
| | SPS | | CoreGel (b) | | |
| System Category | Number with System Category | Estimated Proportion with System Category (c) | Number with System Category | Estimated Proportion with System Category (c) | P-value (d) |
| Skin and Appendages | 54 | 0.0563 | 10 | 0.0213 | 0.0007 |
| Muscle | 147 | 0.1528 | 18 | 0.0373 | 0.0000 |
| Joint | 57 | 0.0607 | 14 | 0.0285 | 0.0102 |
| CNS | 94 | 0.0996 | 20 | 0.0407 | 0.0001 |
| Gastrointestinal | 47 | 0.0499 | 4 | 0.0081 | 0.0001 |
| Body as a Whole | 183 | 0.1870 | 18 | 0.0357 | 0.0000 |
| Metabolic and Nutritional | 15 | 0.0160 | 2 | 0.0044 | 0.0625 |
| Hearing and Vestibular | 19 | 0.0201 | 7 | 0.0140 | 0.4246 |
| Respiratory | 6 | 0.0066 | 2 | 0.0038 | 0.4666 |
| Platelet, Bleeding, Clotting Disorder | 14 | 0.0147 | 2 | 0.0043 | 0.0606 |
| Vascular System | 3 | 0.0036 | 0 | 0.0000 | 1.0000 |
| Cardiovascular | 20 | 0.0201 | 1 | 0.0018 | 0.0033 |
| Vision | 17 | 0.0169 | 4 | 0.0074 | 0.0995 |
| Any of the Above | 329 | 0.3336 | 51 | 0.0992 | 0.0000 |
| Total Patients Assessed | 1264 | | 551 | | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_10.SAS

Creation Date, Time: 09AUG04 18.25

(a) Time from implant surgery to first occurrence of event.
(b) Excludes data on revision patients.
(c) Based on Kaplan-Meier estimates.
(d) p-value is from log-rank test of estimated proportion among patients in SPS versus CoreGel.
Note: System categories were reviewed and approved by the FDA for the SPS report.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.10

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYSTEM CATEGORY
RECONSTRUCTION PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery (a) | | | | |
|---|---|---|---|---|---|
| | SPS | | CoreGel (b) | | |
| System Category | Number with System Category | Estimated Proportion with System Category (c) | Number with System Category | Estimated Proportion with System Category (c) | P-value (d) |
| Skin and Appendages | 30 | 0.1120 | 2 | 0.0124 | 0.0006 |
| Muscle | 67 | 0.2413 | 14 | 0.0718 | 0.0001 |
| Joint | 47 | 0.1974 | 15 | 0.0646 | 0.0594 |
| CNS | 45 | 0.1769 | 4 | 0.0214 | 0.0001 |
| Gastrointestinal | 26 | 0.1015 | 1 | 0.0084 | 0.0023 |
| Body as a Whole | 87 | 0.3384 | 17 | 0.0877 | 0.0000 |
| Metabolic and Nutritional | 9 | 0.0462 | 1 | 0.0043 | 0.1220 |
| Hearing and Vestibular | 6 | 0.0247 | 1 | 0.0046 | 0.1719 |
| Respiratory | 6 | 0.0293 | 0 | 0.0000 | 0.0809 |
| Platelet, Bleeding, Clotting Disorder | 7 | 0.0303 | 1 | 0.0047 | 0.1149 |
| Vascular System | 2 | 0.0081 | 0 | 0.0000 | 1.0000 |
| Cardiovascular | 3 | 0.0103 | 0 | 0.0000 | 0.1585 |
| Vision | 8 | 0.0282 | 2 | 0.0084 | 0.2458 |
| Any of the Above | 138 | 0.5025 | 40 | 0.1976 | 0.0001 |
| Total Patients Assessed | 416 | | 251 | | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_10.SAS Creation Date, Time: 09AUG04 18:25

(a) Time from implant surgery to first occurrence of event.
(b) Excludes data on revision patients.
(c) Based on Kaplan-Meier estimates.
(d) p-value is from log-rank test of estimated proportion among patients in SPS versus CoreGel.
Note: System categories were reviewed and approved by the FDA for the SPS report.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.10

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYSTEM CATEGORY
OVERALL PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery (a) | | | | |
|---|---|---|---|---|---|
| | SPS | | CoreGel (b) | | |
| System Category | Number with System Category | Estimated Proportion with System Category (c) | Number with System Category | Estimated Proportion with System Category (c) | P-value (d) |
| Skin and Appendages | 84 | 0.0687 | 12 | 0.0189 | 0.0000 |
| Muscle | 214 | 0.1735 | 32 | 0.0469 | 0.0000 |
| Joint | 104 | 0.0874 | 29 | 0.0404 | 0.0020 |
| CNS | 139 | 0.1161 | 24 | 0.0355 | 0.0000 |
| Gastrointestinal | 73 | 0.0606 | 5 | 0.0078 | 0.0000 |
| Body as a Whole | 270 | 0.2176 | 35 | 0.0497 | 0.0000 |
| Metabolic and Nutritional | 24 | 0.0206 | 3 | 0.0046 | 0.0197 |
| Hearing and Vestibular | 25 | 0.0212 | 8 | 0.0116 | 0.1656 |
| Respiratory | 12 | 0.0105 | 2 | 0.0027 | 0.0953 |
| Platelet, Bleeding, Clotting Disorder | 21 | 0.0176 | 3 | 0.0045 | 0.0146 |
| Vascular System | 5 | 0.0046 | 0 | 0.0000 | 1.0000 |
| Cardiovascular | 23 | 0.0181 | 1 | 0.0013 | 0.0010 |
| Vision | 25 | 0.0195 | 6 | 0.0078 | 0.0441 |
| Any of the Above | 467 | 0.3706 | 91 | 0.1259 | 0.0000 |
| Total Patients Assessed | 1680 | | 802 | | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_10.SAS

Creation Date, Time: 09AUG04 18:25

(a) Time from implant surgery to first occurrence of event.
(b) Excludes data on revision patients.
(c) Based on Kaplan-Meier estimates.
(d) p-value is from log-rank test of estimated proportion among patients in SPS versus CoreGel.
Note: System categories were reviewed and approved by the FDA for the SPS report.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
AUGMENTATION PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery | | | | |
|---|---|---|---|---|---|
| | SPS (a) | | CoreGel | | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | P-value (c) |
| LOSS OF WEIGHT WITHOUT DIETING | 15 | 0.0160 | 2 | 0.0044 | 0.0625 |
| FATIGUE | 91 | 0.0948 | 9 | 0.0177 | 0.0000 |
| INSOMNIA | 61 | 0.0653 | 8 | 0.0153 | 0.0002 |
| WEAKNESS | 26 | 0.0281 | 3 | 0.0056 | 0.0196 |
| EXHAUSTION | 37 | 0.0388 | 5 | 0.0100 | 0.0017 |
| JOINT SWELLING | 12 | 0.0134 | 4 | 0.0075 | 0.4970 |
| HEEL PAIN | 8 | 0.0086 | 5 | 0.0108 | 0.8925 |
| FREQUENT MUSCLE CRAMPS | 28 | 0.0289 | 5 | 0.0100 | 0.0208 |
| NUMBNESS OF FEET | 14 | 0.0150 | 5 | 0.0100 | 0.4503 |
| RINGING IN EARS | 19 | 0.0201 | 7 | 0.0140 | 0.4246 |
| PAIN/GRITTINESS IN EYES | 8 | 0.0079 | 3 | 0.0055 | 0.5823 |
| DRYNESS OF EYES/NOSE | 30 | 0.0318 | 1 | 0.0019 | 0.0003 |
| PAIN ON SWALLOWING OR CHEWING | 5 | 0.0055 | 0 | 0.0000 | 0.0664 |
| NECK PAIN/STIFFNESS | 58 | 0.0619 | 9 | 0.0188 | 0.0001 |
| PAIN ON BREATHING | 3 | 0.0043 | 0 | 0.0000 | 0.2982 |
| HEART MURMURS | 20 | 0.0201 | 1 | 0.0018 | 0.0033 |
| LOSS OF APPETITE | 16 | 0.0174 | 1 | 0.0019 | 0.0292 |
| PERSISTENT FEVER | 1 | 0.0010 | 0 | 0.0000 | 0.5028 |
| NIGHT SWEATS | 33 | 0.0335 | 7 | 0.0143 | 0.0100 |
| GENERALIZED ACHING | 22 | 0.0231 | 5 | 0.0105 | 0 0889 |
| LOSS OF HEIGHT | 0 | 0.0000 | 0 | 0.0000 | 0.5241 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 09AUG04 18:25

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
AUGMENTATION PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery | | | | |
|---|---|---|---|---|---|
| | SPS (a) | | CoreGel | | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | P-value (c) |
| JOINT PAIN | 48 | 0.0512 | 12 | 0.0248 | 0.0187 |
| FREQUENT MUSCLE PAIN | 8 | 0.0082 | 2 | 0.0038 | 0.0859 |
| NUMBNESS OF HANDS | 26 | 0.0274 | 13 | 0.0266 | 0.5458 |
| JAW PAIN | 21 | 0.0209 | 0 | 0.0000 | 0.0006 |
| OPEN SORES | 1 | 0.0010 | 0 | 0.0000 | 0.4931 |
| REDNESS OF EYES | 8 | 0.0080 | 2 | 0.0044 | 0.1879 |
| DRYNESS OF MOUTH | 15 | 0.0156 | 1 | 0.0019 | 0.0213 |
| BACK PAIN/STIFFNESS | 72 | 0.0754 | 6 | 0.0114 | 0.0000 |
| SEVERE CHEST PAINS | 1 | 0.0010 | 2 | 0.0037 | 0.2018 |
| CHRONIC COUGH | 4 | 0.0039 | 2 | 0.0038 | 0.6876 |
| DIFFICULTY SWALLOWING | 5 | 0.0059 | 0 | 0.0000 | 0.1660 |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 27 | 0.0280 | 3 | 0.0062 | 0.0053 |
| SEVERE RASHES | 4 | 0.0041 | 3 | 0.0056 | 0.8073 |
| SEVERE DRYNESS OF SKIN | 23 | 0.0247 | 3 | 0.0068 | 0.0278 |
| TENDER LUMPS/BUMPS | 8 | 0.0091 | 1 | 0.0019 | 0.0357 |
| EXCESSIVE SENSITIVITY TO SUN | 10 | 0.0106 | 0 | 0.0000 | 0.0258 |
| COLOR CHANGES ON HANDS/FEET WITH COLD EX | 23 | 0.0247 | 0 | 0.0000 | 0.0004 |
| FREQUENT HIVES | 3 | 0.0030 | 1 | 0.0020 | 0.2995 |
| TIGHTNESS OF SKIN | 0 | 0.0000 | 0 | 0.0000 | 0.5453 |
| UNUSUAL HAIR LOSS | 26 | 0.0272 | 3 | 0.0069 | 0.0032 |
| TENDERNESS OF SCALP | 7 | 0.0069 | 0 | 0.0000 | 0.0485 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 09AUG04 18:25

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
AUGMENTATION PATIENTS FDA Item 7b(1)

| | 36 Months after Implant Surgery | | | | |
|---|---|---|---|---|---|
| | SPS (a) | | CoreGel | | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | P-value (c) |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | 14 | 0.0147 | 2 | 0.0043 | 0.0606 |
| COMBINED FATIGUE | 113 | 0.1171 | 9 | 0.0176 | 0.0000 |
| COMBINED PAIN | 161 | 0.1683 | 19 | 0.0372 | 0.0000 |
| COMBINED FIBROMYALGIA | 74 | 0.0761 | 7 | 0.0133 | 0.0000 |
| Any of the Above | 329 | 0.3336 | 51 | 0.0992 | 0.0000 |
| Total Patients Assessed | 1264 | | 551 | | |



(a) SPS does not have revision patients.
(b) Based on Kaplan-Meier estimates.
(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
RECONSTRUCTION PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery | | | | |
|---|---|---|---|---|---|
| | SPS (a) | | CoreGel | | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | P-value (c) |
| LOSS OF WEIGHT WITHOUT DIETING | 9 | 0.0462 | 1 | 0.0043 | 0.1220 |
| FATIGUE | 42 | 0.1635 | 7 | 0.0371 | 0.0014 |
| INSOMNIA | 22 | 0.0833 | 4 | 0.0214 | 0.0231 |
| WEAKNESS | 17 | 0.0690 | 1 | 0.0084 | 0.0104 |
| EXHAUSTION | 25 | 0.1061 | 2 | 0.0090 | 0.0035 |
| JOINT SWELLING | 9 | 0.0383 | 5 | 0.0227 | 0.9971 |
| HEEL PAIN | 9 | 0.0354 | 2 | 0.0130 | 0.1865 |
| FREQUENT MUSCLE CRAMPS | 20 | 0.0760 | 8 | 0.0351 | 0.4258 |
| NUMBNESS OF FEET | 9 | 0.0379 | 0 | 0 0000 | 0.0402 |
| RINGING IN EARS | 6 | 0.0247 | 1 | 0.0046 | 0.1719 |
| PAIN/GRITTINESS IN EYES | 2 | 0.0071 | 2 | 0.0084 | 0.8091 |
| DRYNESS OF EYES/NOSE | 14 | 0.0535 | 2 | 0.0084 | 0.0504 |
| PAIN ON SWALLOWING OR CHEWING | 1 | 0.0034 | 0 | 0.0000 | 0.3643 |
| NECK PAIN/STIFFNESS | 24 | 0.0851 | 4 | 0.0299 | 0.0149 |
| PAIN ON BREATHING | 2 | 0.0095 | 0 | 0.0000 | 0.2758 |
| HEART MURMURS | 3 | 0.0103 | 0 | 0.0000 | 0.1585 |
| LOSS OF APPETITE | 10 | 0.0424 | 0 | 0.0000 | 0.0253 |
| PERSISTENT FEVER | 2 | 0.0069 | 0 | 0.0000 | 0.3415 |
| NIGHT SWEATS | 33 | 0.1353 | 5 | 0.0277 | 0.0029 |
| GENERALIZED ACHING | 17 | 0.0653 | 3 | 0.0130 | 0.0361 |
| LOSS OF HEIGHT | 6 | 0.0324 | 4 | 0.0175 | 0.9362 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 09AUG04 18:25

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
RECONSTRUCTION PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery | | | | |
|---|---|---|---|---|---|
| | SPS (a) | | CoreGel | | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | P-value (c) |
| JOINT PAIN | 33 | 0.1426 | 14 | 0.0602 | 0.3658 |
| FREQUENT MUSCLE PAIN | 9 | 0.0312 | 3 | 0.0128 | 0.1418 |
| NUMBNESS OF HANDS | 20 | 0.0845 | 0 | 0.0000 | 0.0019 |
| JAW PAIN | 3 | 0.0155 | 1 | 0.0084 | 0.7904 |
| OPEN SORES | 0 | 0.0000 | 0 | 0.0000 | |
| REDNESS OF EYES | 6 | 0.0211 | 0 | 0.0000 | 0.0807 |
| DRYNESS OF MOUTH | 14 | 0.0675 | 0 | 0.0000 | 0.0094 |
| BACK PAIN/STIFFNESS | 20 | 0.0859 | 3 | 0.0127 | 0.0283 |
| SEVERE CHEST PAINS | 1 | 0.0035 | 0 | 0.0000 | 0.3849 |
| CHRONIC COUGH | 5 | 0.0233 | 0 | 0.0000 | 0.1304 |
| DIFFICULTY SWALLOWING | 2 | 0.0068 | 0 | 0.0000 | 0.2609 |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 17 | 0.0650 | 1 | 0.0084 | 0.0288 |
| SEVERE RASHES | 2 | 0.0173 | 0 | 0.0000 | 0.3920 |
| SEVERE DRYNESS OF SKIN | 16 | 0 0562 | 0 | 0.0000 | 0.0034 |
| TENDER LUMPS/BUMPS | 5 | 0.0174 | 1 | 0 0068 | 0.4259 |
| EXCESSIVE SENSITIVITY TO SUN | 3 | 0.0106 | 0 | 0.0000 | 0.1152 |
| COLOR CHANGES ON HANDS/FEET WITH COLD EX | 6 | 0.0263 | 0 | 0.0000 | 0.1004 |
| FREQUENT HIVES | 0 | 0.0000 | 0 | 0.0000 | |
| TIGHTNESS OF SKIN | 4 | 0.0145 | 0 | 0.0000 | 0.1714 |
| UNUSUAL HAIR LOSS | 9 | 0.0365 | 2 | 0.0124 | 0.2194 |
| TENDERNESS OF SCALP | 2 | 0.0084 | 1 | 0.0043 | 0.9653 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 09AUG04 18.25

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
RECONSTRUCTION PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery | | | | |
|---|---|---|---|---|---|
| | SPS (a) | | CoreGel | | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | P-value (c) |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | 7 | 0.0303 | 1 | 0.0047 | 0.1149 |
| COMBINED FATIGUE | 53 | 0.2020 | 7 | 0.0371 | 0.0001 |
| COMBINED PAIN | 74 | 0.2781 | 23 | 0.1108 | 0.0054 |
| COMBINED FIBROMYALGIA | 37 | 0.1322 | 4 | 0.0176 | 0.0005 |
| Any of the Above | 138 | 0.5025 | 40 | 0.1976 | 0.0001 |
| Total Patients Assessed | 416 | | 251 | | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 09AUG04 18:25

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
REVISION PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery | | | | |
|---|---|---|---|---|---|
| | SPS (a) | | CoreGel | | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | P-value (c) |
| LOSS OF WEIGHT WITHOUT DIETING | 0 | 0.0000 | 3 | 0.0156 | |
| FATIGUE | 0 | 0.0000 | 11 | 0.0595 | |
| INSOMNIA | 0 | 0.0000 | 5 | 0.0258 | |
| WEAKNESS | 0 | 0.0000 | 5 | 0.0275 | |
| EXHAUSTION | 0 | 0.0000 | 6 | 0.0327 | |
| JOINT SWELLING | 0 | 0.0000 | 4 | 0.0229 | |
| HEEL PAIN | 0 | 0.0000 | 2 | 0.0099 | |
| FREQUENT MUSCLE CRAMPS | 0 | 0.0000 | 5 | 0.0278 | |
| NUMBNESS OF FEET | 0 | 0.0000 | 4 | 0.0225 | |
| RINGING IN EARS | 0 | 0.0000 | 5 | 0.0267 | |
| PAIN/GRITTINESS IN EYES | 0 | 0.0000 | 0 | 0.0000 | |
| DRYNESS OF EYES/NOSE | 0 | 0.0000 | 2 | 0.0102 | |
| PAIN ON SWALLOWING OR CHEWING | 0 | 0.0000 | 2 | 0.0107 | |
| NECK PAIN/STIFFNESS | 0 | 0.0000 | 4 | 0.0202 | |
| PAIN ON BREATHING | 0 | 0.0000 | 1 | 0.0053 | |
| HEART MURMURS | 0 | 0.0000 | 0 | 0.0000 | |
| LOSS OF APPETITE | 0 | 0.0000 | 2 | 0.0106 | |
| PERSISTENT FEVER | 0 | 0.0000 | 0 | 0.0000 | |
| NIGHT SWEATS | 0 | 0.0000 | 4 | 0.0200 | |
| GENERALIZED ACHING | 0 | 0.0000 | 7 | 0.0387 | |
| LOSS OF HEIGHT | 0 | 0.0000 | 1 | 0.0053 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time. 09AUG04 18:25

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
REVISION PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery | | | | |
|---|---|---|---|---|---|
| | SPS (a) | | CoreGel | | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | P-value (c) |
| JOINT PAIN | 0 | 0.0000 | 10 | 0.0531 | |
| FREQUENT MUSCLE PAIN | 0 | 0.0000 | 2 | 0.0099 | |
| NUMBNESS OF HANDS | 0 | 0.0000 | 8 | 0.0431 | |
| JAW PAIN | 0 | 0.0000 | 1 | 0.0050 | |
| OPEN SORES | 0 | 0.0000 | 0 | 0.0000 | |
| REDNESS OF EYES | 0 | 0.0000 | 2 | 0.0107 | |
| DRYNESS OF MOUTH | 0 | 0.0000 | 2 | 0.0103 | |
| BACK PAIN/STIFFNESS | 0 | 0.0000 | 8 | 0.0469 | |
| SEVERE CHEST PAINS | 0 | 0.0000 | 0 | 0.0000 | |
| CHRONIC COUGH | 0 | 0.0000 | 0 | 0.0000 | |
| DIFFICULTY SWALLOWING | 0 | 0.0000 | 2 | 0.0107 | |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 0 | 0.0000 | 4 | 0.0204 | |
| SEVERE RASHES | 0 | 0.0000 | 0 | 0.0000 | |
| SEVERE DRYNESS OF SKIN | 0 | 0.0000 | 5 | 0.0328 | |
| TENDER LUMPS/BUMPS | 0 | 0.0000 | 5 | 0.0269 | |
| EXCESSIVE SENSITIVITY TO SUN | 0 | 0.0000 | 1 | 0.0050 | |
| COLOR CHANGES ON HANDS/FEET WITH COLD EX | 0 | 0.0000 | 2 | 0.0101 | |
| FREQUENT HIVES | 0 | 0.0000 | 1 | 0.0049 | |
| TIGHTNESS OF SKIN | 0 | 0.0000 | 0 | 0.0000 | |
| UNUSUAL HAIR LOSS | 0 | 0.0000 | 3 | 0.0188 | |
| TENDERNESS OF SCALP | 0 | 0.0000 | 1 | 0.0049 | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 09AUG04 18:25

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
REVISION PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery | | | | |
|---|---|---|---|---|---|
| | SPS (a) | | CoreGel | | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | P-value (c) |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | 0 | 0.0000 | 4 | 0.0220 | |
| COMBINED FATIGUE | 0 | 0.0000 | 11 | 0.0595 | |
| COMBINED PAIN | 0 | 0.0000 | 18 | 0.0990 | |
| COMBINED FIBROMYALGIA | 0 | 0.0000 | 7 | 0.0359 | |
| Any of the Above | 0 | 0.0000 | 36 | 0.1982 | |
| Total Patients Assessed | 0 | | 205 | | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time. 09AUG04 18:25

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
OVERALL PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery | | | | |
|---|---|---|---|---|---|
| | SPS (a) | | CoreGel | | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | P-value (c) |
| LOSS OF WEIGHT WITHOUT DIETING | 24 | 0.0206 | 6 | 0.0068 | 0.0454 |
| FATIGUE | 133 | 0.1089 | 27 | 0.0304 | 0.0000 |
| INSOMNIA | 83 | 0.0700 | 17 | 0.0186 | 0.0000 |
| WEAKNESS | 43 | 0.0363 | 9 | 0.0103 | 0.0030 |
| EXHAUSTION | 62 | 0.0513 | 13 | 0.0146 | 0.0001 |
| JOINT SWELLING | 21 | 0.0184 | 13 | 0.0142 | 0.8457 |
| HEEL PAIN | 17 | 0.0141 | 9 | 0.0109 | 0.3273 |
| FREQUENT MUSCLE CRAMPS | 48 | 0.0391 | 18 | 0.0198 | 0.0364 |
| NUMBNESS OF FEET | 23 | 0.0195 | 9 | 0.0105 | 0.2119 |
| RINGING IN EARS | 25 | 0.0212 | 13 | 0.0147 | 0.3594 |
| PAIN/GRITTINESS IN EYES | 10 | 0.0077 | 5 | 0.0051 | 0.4593 |
| DRYNESS OF EYES/NOSE | 44 | 0.0366 | 5 | 0.0052 | 0.0000 |
| PAIN ON SWALLOWING OR CHEWING | 6 | 0.0051 | 2 | 0.0022 | 0.1775 |
| NECK PAIN/STIFFNESS | 82 | 0.0683 | 17 | 0.0206 | 0.0000 |
| PAIN ON BREATHING | 5 | 0.0054 | 1 | 0 0011 | 0.2804 |
| HEART MURMURS | 23 | 0.0181 | 1 | 0.0010 | 0.0002 |
| LOSS OF APPETITE | 26 | 0.0222 | 3 | 0.0032 | 0.0032 |
| PERSISTENT FEVER | 3 | 0.0023 | 0 | 0.0000 | 0.1892 |
| NIGHT SWEATS | 66 | 0.0534 | 16 | 0.0181 | 0.0000 |
| GENERALIZED ACHING | 39 | 0.0318 | 15 | 0.0174 | 0.0477 |
| LOSS OF HEIGHT | 6 | 0.0055 | 5 | 0.0052 | 0.9880 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 09AUG04 18:25

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
OVERALL PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery | | | | |
|---|---|---|---|---|---|
| | SPS (a) | | CoreGel | | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | P-value (c) |
| JOINT PAIN | 81 | 0.0689 | 36 | 0.0400 | 0.0301 |
| FREQUENT MUSCLE PAIN | 17 | 0.0134 | 7 | 0.0072 | 0.0231 |
| NUMBNESS OF HANDS | 46 | 0.0384 | 21 | 0.0243 | 0.0778 |
| JAW PAIN | 24 | 0.0190 | 2 | 0.0025 | 0.0005 |
| OPEN SORES | 1 | 0.0007 | 0 | 0.0000 | 0.4371 |
| REDNESS OF EYES | 14 | 0.0110 | 4 | 0.0047 | 0.0617 |
| DRYNESS OF MOUTH | 29 | 0.0249 | 3 | 0.0032 | 0.0006 |
| BACK PAIN/STIFFNESS | 92 | 0.0767 | 17 | 0.0192 | 0.0000 |
| SEVERE CHEST PAINS | 2 | 0.0015 | 2 | 0.0021 | 0.8915 |
| CHRONIC COUGH | 9 | 0.0072 | 2 | 0.0021 | 0.1175 |
| DIFFICULTY SWALLOWING | 7 | 0.0065 | 2 | 0.0022 | 0.3193 |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 44 | 0.0358 | 8 | 0.0092 | 0.0007 |
| SEVERE RASHES | 6 | 0.0056 | 3 | 0.0032 | 0.3674 |
| SEVERE DRYNESS OF SKIN | 39 | 0.0323 | 8 | 0.0107 | 0.0020 |
| TENDER LUMPS/BUMPS | 13 | 0.0113 | 7 | 0.0079 | 0.2638 |
| EXCESSIVE SENSITIVITY TO SUN | 13 | 0.0110 | 1 | 0.0010 | 0.0069 |
| COLOR CHANGES ON HANDS/FEET WITH COLD EX | 29 | 0.0250 | 2 | 0.0020 | 0.0001 |
| FREQUENT HIVES | 3 | 0.0023 | 2 | 0.0022 | 0.4446 |
| TIGHTNESS OF SKIN | 4 | 0.0032 | 0 | 0.0000 | 0.0991 |
| UNUSUAL HAIR LOSS | 35 | 0.0291 | 8 | 0.0105 | 0.0018 |
| TENDERNESS OF SCALP | 9 | 0.0071 | 2 | 0.0020 | 0.1208 |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 09AUG04 18.25

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE
OVERALL PATIENTS - FDA Item 7b(1)

| | 36 Months after Implant Surgery | | | | |
|---|---|---|---|---|---|
| | SPS (a) | | CoreGel | | |
| Symptom Type | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | Number with Symptom Type | Estimated Proportion with Symptom Type (b) | P-value (c) |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | 21 | 0.0176 | 7 | 0.0082 | 0.0605 |
| COMBINED FATIGUE | 166 | 0.1351 | 27 | 0.0304 | 0.0000 |
| COMBINED PAIN | 235 | 0.1925 | 60 | 0.0664 | 0.0000 |
| COMBINED FIBROMYALGIA | 111 | 0.0892 | 18 | 0.0190 | 0.0000 |
| Any of the Above | 467 | 0.3706 | 127 | 0.1407 | 0.0000 |
| Total Patients Assessed | 1680 | | 1007 | | |

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 09AUG04 18:25

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| Symptom Type | | | |
| LOSS OF WEIGHT WITHOUT DIETING | Baseline | 4/1007 (0.40) | 0.8250 |
| | 1 Year | 4/ 965 (0.41) | . |
| | 2 Year | 5/ 941 (0.53) | . |
| | 3 Year | 2/ 665 (0.30) | . |
| FATIGUE | Baseline | 8/1007 (0.79) | 0.0002 |
| | 1 Year | 17/ 965 (1.76) | . |
| | 2 Year | 26/ 941 (2.76) | . |
| | 3 Year | 15/ 665 (2.26) | . |
| INSOMNIA | Baseline | 24/1007 (2.38) | 0.6081 |
| | 1 Year | 22/ 965 (2.28) | . |
| | 2 Year | 26/ 941 (2.76) | . |
| | 3 Year | 10/ 665 (1.50) | . |
| WEAKNESS | Baseline | 1/1007 (0.10) | 0.0085 |
| | 1 Year | 3/ 965 (0.31) | . |
| | 2 Year | 8/ 941 (0.85) | . |
| | 3 Year | 7/ 665 (1.05) | . |
| EXHAUSTION | Baseline | 1/1007 (0.10) | 0 0057 |
| | 1 Year | 2/ 965 (0.21) | . |
| | 2 Year | 12/ 941 (1.28) | . |
| | 3 Year | 7/ 665 (1.05) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| JOINT SWELLING | Baseline | 6/1007 (0.60) | 0.1263 |
| | 1 Year | 8/ 965 (0.83) | . |
| | 2 Year | 14/ 941 (1.49) | . |
| | 3 Year | 6/ 665 (0.90) | . |
| HEEL PAIN | Baseline | 2/1007 (0.20) | 0.0138 |
| | 1 Year | 4/ 965 (0.41) | . |
| | 2 Year | 8/ 941 (0.85) | . |
| | 3 Year | 7/ 665 (1.05) | . |
| FREQUENT MUSCLE CRAMPS | Baseline | 3/1007 (0.30) | 0.0009 |
| | 1 Year | 8/ 965 (0.83) | . |
| | 2 Year | 17/ 941 (1.81) | . |
| | 3 Year | 9/ 665 (1.35) | . |
| NUMBNESS OF FEET | Baseline | 2/1007 (0.20) | 0.0278 |
| | 1 Year | 4/ 965 (0.41) | . |
| | 2 Year | 8/ 941 (0.85) | . |
| | 3 Year | 5/ 665 (0.75) | . |
| RINGING IN EARS | Baseline | 10/1007 (0.99) | 0.4562 |
| | 1 Year | 12/ 965 (1.24) | . |
| | 2 Year | 13/ 941 (1.38) | . |
| | 3 Year | 9/ 665 (1.35) | . |
| PAIN/GRITTINESS IN EYES | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 4/ 965 (0.41) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| PAIN/GRITTINESS IN EYES | 2 Year | 4/ 941 (0.43) | . |
| | 3 Year | 2/ 665 (0.30) | . |
| DRYNESS OF EYES/NOSE | Baseline | 14/1007 (1.39) | 0.0529 |
| | 1 Year | 12/ 965 (1.24) | . |
| | 2 Year | 13/ 941 (1.38) | . |
| | 3 Year | 3/ 665 (0.45) | . |
| PAIN ON SWALLOWING OR CHEWING | Baseline | 1/1007 (0.10) | 0.5140 |
| | 1 Year | 1/ 965 (0.10) | . |
| | 2 Year | 3/ 941 (0.32) | . |
| | 3 Year | 1/ 665 (0.15) | . |
| NECK PAIN/STIFFNESS | Baseline | 18/1007 (1.79) | 0.6353 |
| | 1 Year | 18/ 965 (1.87) | . |
| | 2 Year | 17/ 941 (1.81) | . |
| | 3 Year | 11/ 665 (1.65) | . |
| PAIN ON BREATHING | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | |
| | 2 Year | 1/ 941 (0.11) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| HEART MURMURS | Baseline | 23/1007 (2.28) | 0.0006 |
| | 1 Year | 18/ 965 (1.87) | . |
| | 2 Year | 15/ 941 (1.59) | . |
| | 3 Year | 4/ 665 (0.60) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| LOSS OF APPETITE | Baseline | 1/1007 (0.10) | 0.2390 |
| | 1 Year | 1/ 965 (0.10) | . |
| | 2 Year | 4/ 941 (0.43) | |
| | 3 Year | 2/ 665 (0.30) | . |
| PERSISTENT FEVER | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 0/ 941 ( 0) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| NIGHT SWEATS | Baseline | 16/1007 (1.59) | 0.6120 |
| | 1 Year | 20/ 965 (2.07) | . |
| | 2 Year | 14/ 941 (1.49) | . |
| | 3 Year | 7/ 665 (1.05) | . |
| GENERALIZED ACHING | Baseline | 7/1007 (0.70) | 0.0309 |
| | 1 Year | 8/ 965 (0.83) | . |
| | 2 Year | 19/ 941 (2.02) | . |
| | 3 Year | 10/ 665 (1.50) | . |
| LOSS OF HEIGHT | Baseline | 2/1007 (0.20) | 0.1929 |
| | 1 Year | 4/ 965 (0.41) | . |
| | 2 Year | 6/ 941 (0.64) | . |
| | 3 Year | 2/ 665 (0.30) | . |
| JOINT PAIN | Baseline | 13/1007 (1.29) | 0.0002 |
| | 1 Year | 24/ 965 (2.49) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| JOINT PAIN | 2 Year | 35/ 941 (3.72) | . |
| | 3 Year | 22/ 665 (3.31) | . |
| FREQUENT MUSCLE PAIN | Baseline | 5/1007 (0.50) | 0.5295 |
| | 1 Year | 10/ 965 (1.04) | . |
| | 2 Year | 10/ 941 (1.06) | . |
| | 3 Year | 2/ 665 (0.30) | . |
| NUMBNESS OF HANDS | Baseline | 10/1007 (0.99) | 0.0870 |
| | 1 Year | 11/ 965 (1.14) | . |
| | 2 Year | 21/ 941 (2.23) | . |
| | 3 Year | 14/ 665 (2.11) | . |
| JAW PAIN | Baseline | 6/1007 (0.60) | 0.2939 |
| | 1 Year | 6/ 965 (0.62) | . |
| | 2 Year | 3/ 941 (0.32) | . |
| | 3 Year | 2/ 665 (0.30) | . |
| OPEN SORES | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 0/ 941 ( 0) | |
| | 3 Year | 0/ 665 ( 0) | . |
| REDNESS OF EYES | Baseline | 3/1007 (0.30) | 0.4338 |
| | 1 Year | 3/ 965 (0.31) | . |
| | 2 Year | 7/ 941 (0.74) | . |
| | 3 Year | 3/ 665 (0.45) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| DRYNESS OF MOUTH | Baseline | 3/1007 (0.30) | 0.9685 |
| | 1 Year | 2/ 965 (0.21) | . |
| | 2 Year | 4/ 941 (0.43) | . |
| | 3 Year | 3/ 665 (0.45) | . |
| BACK PAIN/STIFFNESS | Baseline | 18/1007 (1.79) | 0.8497 |
| | 1 Year | 18/ 965 (1.87) | . |
| | 2 Year | 27/ 941 (2.87) | . |
| | 3 Year | 10/ 665 (1.50) | . |
| SEVERE CHEST PAINS | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 1/ 965 (0.10) | . |
| | 2 Year | 2/ 941 (0.21) | . |
| | 3 Year | 1/ 665 (0.15) | . |
| CHRONIC COUGH | Baseline | 1/1007 (0.10) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 2/ 941 (0.21) | . |
| | 3 Year | 2/ 665 (0.30) | . |
| DIFFICULTY SWALLOWING | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 2/ 941 (0.21) | . |
| | 3 Year | 1/ 665 (0.15) | . |
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | Baseline | 8/1007 (0.79) | 0.7543 |
| | 1 Year | 8/ 965 (0.83) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| FREQUENT,SEVERE DIARRHEA/CONSTIPATION | 2 Year | 9/ 941 (0.96) | . |
| | 3 Year | 7/ 665 (1.05) | . |
| SEVERE RASHES | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 1/ 965 (0.10) | . |
| | 2 Year | 2/ 941 (0.21) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| SEVERE DRYNESS OF SKIN | Baseline | 2/1007 (0.20) | 0 0170 |
| | 1 Year | 5/ 965 (0.52) | . |
| | 2 Year | 7/ 941 (0.74) | . |
| | 3 Year | 4/ 665 (0.60) | . |
| TENDER LUMPS/BUMPS | Baseline | 1/1007 (0.10) | 0.0291 |
| | 1 Year | 3/ 965 (0.31) | . |
| | 2 Year | 7/ 941 (0.74) | . |
| | 3 Year | 3/ 665 (0.45) | . |
| EXCESSIVE SENSITIVITY TO SUN | Baseline | 3/1007 (0.30) | 0.9790 |
| | 1 Year | 3/ 965 (0.31) | . |
| | 2 Year | 4/ 941 (0.43) | . |
| | 3 Year | 2/ 665 (0.30) | . |
| COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE | Baseline | 10/1007 (0.99) | 0.8653 |
| | 1 Year | 9/ 965 (0.93) | . |
| | 2 Year | 10/ 941 (1.06) | |
| | 3 Year | 7/ 665 (1.05) | . |

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 05NOV04 10:37

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| FREQUENT HIVES | Baseline | 1/1007 (0.10) | . |
| | 1 Year | 1/ 965 (0.10) | . |
| | 2 Year | 2/ 941 (0.21) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| TIGHTNESS OF SKIN | Baseline | 1/1007 (0.10) | . |
| | 1 Year | 1/ 965 (0.10) | . |
| | 2 Year | 0/ 941 ( 0) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| UNUSUAL HAIR LOSS | Baseline | 3/1007 (0.30) | 0.0151 |
| | 1 Year | 5/ 965 (0.52) | . |
| | 2 Year | 7/ 941 (0.74) | . |
| | 3 Year | 9/ 665 (1.35) | . |
| TENDERNESS OF SCALP | Baseline | 1/1007 (0.10) | 0.5786 |
| | 1 Year | 2/ 965 (0.21) | . |
| | 2 Year | 2/ 941 (0.21) | . |
| | 3 Year | 2/ 665 (0.30) | . |
| SEVERE BRUISING WITH LITTLE OR NO INJURY | Baseline | 8/1007 (0.79) | 0.8377 |
| | 1 Year | 8/ 965 (0.83) | . |
| | 2 Year | 8/ 941 (0.85) | . |
| | 3 Year | 5/ 665 (0.75) | . |
| COMBINED FATIGUE | Baseline | 8/1007 (0.79) | 0.0002 |
| | 1 Year | 17/ 965 (1.76) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| COMBINED FATIGUE | 2 Year | 26/ 941 (2.76) | . |
| | 3 Year | 15/ 665 (2.26) | . |
| COMBINED PAIN | Baseline | 44/1007 (4.37) | 0.2607 |
| | 1 Year | 54/ 965 (5.60) | . |
| | 2 Year | 63/ 941 (6.70) | . |
| | 3 Year | 31/ 665 (4.66) | . |
| COMBINED FIBROMYALGIA | Baseline | 5/1007 (0.50) | 0.0011 |
| | 1 Year | 9/ 965 (0.93) | . |
| | 2 Year | 19/ 941 (2.02) | . |
| | 3 Year | 12/ 665 (1.80) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| Symptom Category | | | |
| Skin and Appendages | Baseline | 7/1007 (0.70) | 0.0006 |
| | 1 Year | 13/ 965 (1.35) | . |
| | 2 Year | 17/ 941 (1.81) | . |
| | 3 Year | 13/ 665 (1.95) | . |
| Muscle | Baseline | 41/1007 (4.07) | 0.7863 |
| | 1 Year | 43/ 965 (4.46) | . |
| | 2 Year | 51/ 941 (5.42) | . |
| | 3 Year | 26/ 665 (3.91) | |
| Joint | Baseline | 16/1007 (1.59) | 0.0009 |
| | 1 Year | 27/ 965 (2.80) | . |
| | 2 Year | 39/ 941 (4.14) | . |
| | 3 Year | 22/ 665 (3.31) | . |
| CNS | Baseline | 34/1007 (3.38) | 0.3976 |
| | 1 Year | 34/ 965 (3.52) | . |
| | 2 Year | 47/ 941 (4.99) | . |
| | 3 Year | 22/ 665 (3.31) | . |
| Gastrointestinal | Baseline | 8/1007 (0.79) | 0.4881 |
| | 1 Year | 8/ 965 (0.83) | . |
| | 2 Year | 11/ 941 (1.17) | . |
| | 3 Year | 8/ 665 (1.20) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11 12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| Body as a Whole | Baseline | 52/1007 (5.16) | 0.5369 |
| | 1 Year | 57/ 965 (5.91) | . |
| | 2 Year | 69/ 941 (7.33) | . |
| | 3 Year | 35/ 665 (5.26) | . |
| Metabolic and Nutritional | Baseline | 4/1007 (0.40) | 0.8250 |
| | 1 Year | 4/ 965 (0.41) | . |
| | 2 Year | 5/ 941 (0.53) | . |
| | 3 Year | 2/ 665 (0.30) | . |
| Hearing and Vestibular | Baseline | 10/1007 (0.99) | 0.4562 |
| | 1 Year | 12/ 965 (1.24) | . |
| | 2 Year | 13/ 941 (1.38) | . |
| | 3 Year | 9/ 665 (1.35) | . |
| Respiratory | Baseline | 1/1007 (0.10) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 3/ 941 (0.32) | . |
| | 3 Year | 2/ 665 (0.30) | . |
| Platelet, Bleeding, Clotting Disorder | Baseline | 8/1007 (0.79) | 0.8377 |
| | 1 Year | 8/ 965 (0.83) | . |
| | 2 Year | 8/ 941 (0.85) | . |
| | 3 Year | 5/ 665 (0.75) | . |
| Cardiovascular | Baseline | 23/1007 (2.28) | 0.0006 |
| | 1 Year | 18/ 965 (1.87) | |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| Cardiovascular | 2 Year | 15/ 941 (1.59) | . |
| | 3 Year | 4/ 665 (0.60) | . |
| Vision | Baseline | 3/1007 (0.30) | 0.0396 |
| | 1 Year | 7/ 965 (0.73) | . |
| | 2 Year | 11/ 941 (1.17) | . |
| | 3 Year | 4/ 665 (0.60) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| Physical Examination Finding | | | |
| WEAK HEADLIFT | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 2/ 965 (0.21) | . |
| | 2 Year | 3/ 941 (0.32) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| INABILITY TO RAISE ARMS | Baseline | 1/1007 (0.10) | . |
| | 1 Year | 1/ 965 (0.10) | . |
| | 2 Year | 1/ 941 (0.11) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| INABILITY TO GET OUT OF CHAIR | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 1/ 941 (0.11) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| WRIST SWELLING | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 1/ 965 (0.10) | . |
| | 2 Year | 2/ 941 (0.21) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| DIGITS SWELLING | Baseline | 4/1007 (0.40) | 0.0640 |
| | 1 Year | 8/ 965 (0.83) | . |
| | 2 Year | 9/ 941 (0.96) | . |
| | 3 Year | 6/ 665 (0.90) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| ELBOWS SWELLING | Baseline | 2/1007 (0.20) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 3/ 941 (0.32) | |
| | 3 Year | 0/ 665 ( 0) | . |
| KNEES SWELLING | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 2/ 965 (0.21) | . |
| | 2 Year | 4/ 941 (0.43) | . |
| | 3 Year | 4/ 665 (0.60) | . |
| ANKLES SWELLING | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 1/ 965 (0.10) | . |
| | 2 Year | 4/ 941 (0.43) | . |
| | 3 Year | 2/ 665 (0.30) | . |
| BOUTONNIERE | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 1/ 941 (0.11) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| ULNAR DRIFT | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 0/ 941 ( 0) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| SWAN NECK | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 05NOV04 10:37

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| SWAN NECK | 2 Year | 0/ 941 ( 0) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| TRIGGER FINGERS | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 1/ 941 (0.11) | . |
| | 3 Year | 1/ 665 (0.15) | . |
| JOINT TENDERNESS | Baseline | 2/1007 (0.20) | 0.0039 |
| | 1 Year | 5/ 965 (0.52) | . |
| | 2 Year | 15/ 941 (1.59) | . |
| | 3 Year | 10/ 665 (1.50) | . |
| GRIP STRENGTH AND MOTION-FINGER TO PALM CREASE | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 1/ 941 (0.11) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| NECK MOTION-CHIN TO CHEST OR STERNUM | Baseline | 1/1007 (0.10) | . |
| | 1 Year | 2/ 965 (0.21) | |
| | 2 Year | 2/ 941 (0.21) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| CHEST EXPANSION | Baseline | 2/1007 (0.20) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 0/ 941 ( 0) | . |
| | 3 Year | 0/ 665 ( 0) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| OCCIPUT TO WALL | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 1/ 965 (0.10) | . |
| | 2 Year | 2/ 941 (0.21) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| JAW MOTION | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 0/ 941 ( 0) | . |
| | 3 Year | 0/ 665 ( 0) | |
| BACK MOTION | Baseline | 0/1007 ( 0) | |
| | 1 Year | 1/ 965 (0.10) | . |
| | 2 Year | 1/ 941 (0.11) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| HAIR LOSS | Baseline | 3/1007 (0.30) | 0.6767 |
| | 1 Year | 4/ 965 (0.41) | . |
| | 2 Year | 3/ 941 (0.32) | . |
| | 3 Year | 4/ 665 (0.60) | . |
| SKIN TIGHTNESS | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 0/ 941 ( 0) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| RAYNAUD'S PHENOMENON | Baseline | 2/1007 (0.20) | 0.6128 |
| | 1 Year | 1/ 965 (0.10) | . |

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(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

| Parameter | Visit | Number of Patients With Event n/N(%) | p-value (1) |
|---|---|---|---|
| RAYNAUD'S PHENOMENON | 2 Year | 2/ 941 (0.21) | . |
| | 3 Year | 1/ 665 (0.15) | . |
| CALCINOSIS OVER TIBIA,ULNA,ELBOWS | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 0/ 941 ( 0) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| SWOLLEN DIGITS | Baseline | 1/1007 (0.10) | 0.0305 |
| | 1 Year | 2/ 965 (0.21) | . |
| | 2 Year | 6/ 941 (0.64) | . |
| | 3 Year | 3/ 665 (0.45) | . |
| ERYTHEMA OVER KNUCKLES | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 0/ 941 ( 0) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| BLUISH HUE COLOR ON EYELIDS | Baseline | 0/1007 ( 0) | |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 0/ 941 ( 0) | . |
| | 3 Year | 0/ 665 ( 0) | . |
| NON-TENDER LUMPS OR BUMPS ON ELBOWS | Baseline | 0/1007 ( 0) | . |
| | 1 Year | 0/ 965 ( 0) | . |
| | 2 Year | 0/ 941 ( 0) | . |
| | 3 Year | 0/ 665 ( 0) | . |



(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.